DISSERTATION

A STUDY TO ASSESS THE EFFECTIVENESS OF CRYOTHERAPY AS TOPICAL ANANESTHETICS PRIOR TO INTRAVENOUS CANNULATION AMONG CHILDREN 5-12 YEARS OF AGE RECEIVING INTRAVENOUS CHEMOTHERAPY ADMITTED IN HAEMATOLOGY WARD, INSTITUTE OF CHILD HEALTH AND HOSPITAL FOR CHILDREN, EGMORE, CHENNAI-08".

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CERTIFICATE

This is to certify that this dissertation titled **"A Study To Assess The Effectiveness Of Cryotherapy As Topical Ananesthetics Prior To Intravenous Cannulation Among Children 5-12 Years Of Age Receiving Intravenous Chemotherapy Admitted In Haematology Ward, Institute Of Child Health and Hospital for Children, Egmore, Chennai-08"** is a bonafide work done by MRS.S.AMUTHA, College of Nursing, Madras Medical College, Chennai – 600003 submitted to THE TAMILNADU DR.M.G.R. MEDICAL UNVERSITY, CHENNAI in Partial fulfilment of the requirements for the award of Degree of Master of Science in Nursing, Branch - II, CHILD HEALTH NURSING, under our guidance and supervision during the academic period from 2012 – 2014.

DR. MS. R.LAKSHMI M. Sc (N)., Ph.D.,
Principal,
College of Nursing,
Madras Medical College,
Chennai-03.

DR.R.JEYARAMAN, MS.,Mch.,
Dean,
Madras Medical College,
Rajiv Gandhi Govt. General Hospital,
Chennai-03.

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Health is Wealth

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ABBREVIATIONS	EXPANSION
DF	Degrees of freedom
SD	Standard deviation
CI	Confidence Interval
Fig	Figure
H1 & H2	Research Hypothesis
M. Sc (N)	Master of science in Nursing
$\chi 2$	Chi-square test
NO	Number
IV	Intravenous
ALL	Acute Lymphocytic Leukaemia

ABSTRACT

Title: "A study to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy admitted in haematology ward, Institute of Child Health, Egmore, Chennai-8".

Method: According to the statement of problem and the objectives to be achieved ***True Experimental – Post-Test Only Control Group*** design was adopted. In the study 60 children between 5-12 years, were selected and assigned in two groups as ***Experimental group (topical ice pack application)*** and *Control group* ***(routine care)*** during intravenous cannulation by *Simple Random Sampling technique*. The study was conducted at the ***Haematology Department, Institute of Child Health and Hospital for Children, Egmore-08.*** The conceptual framework adapted for the study was based on ***Roy's Adaptation model***. Data were collected and ***Wong Baker's faces pain scale*** was used to assess the intensity of pain upon the effectiveness of topical ice pack application during intravenous cannulation in both experimental group and control group. **Result:** The collected data were analysed statistically by using "student ***Chi Square Test***" and independent ***"t" test.*** The study revealed that the post-test mean pain score of the experiment group was ***2.53*** and the control group was ***7.13***. The difference in the pain score is ***4.60***. This difference is large and was statistically very highly significant with ***P=0.001***. **Conclusion:** The study revealed that topical ice pack application had a highly significant effect in reducing the intensity of pain among children during intravenous annulation.

CHAPTER – I
INTRODUCTION

"Pain is such an uncomfortable feeling that even a tiny of it is enough to ruin every enjoyment".

-Will Rogers.

Illness and hospitalization expose children to unfamiliar and unpleasant feelings. Since children have little experience with comprehension of the pain and disease process, such negative feeling can cause intimidation and anxiety for them. Children requiring needle stick such as injections, IV catheters and blood sampling view these procedure as frightening and as a significant source of pain. Millions of children experience these procedures considerably distressing.

Pain occurs in all clinical settings among different groups of patients. Nurses have a central role in pain assessment and management. Pain is one of the most common widely under-treated health problems. Pain is considerably more complex than a predictable reaction to sensory stimulation. An individual's reaction to painful stimuli is influenced by their perception of pain and is mediated by a host of proximal and distal factors such as age, developmental stage, emotional state, temperament, culture, previous experiences, type of procedure, coping skills, environment, and responses of caregivers and practitioners. Regardless of the illness or reason for the medical procedure or intervention, it is widely recognized that even the most "minor" procedures can cause significant distress, fear, and pain.

Chemotherapy has been recognized as an essential means of treating cancer. Chemotherapy was introduced in the early 1940s. Chemotherapy has the main purpose of destroying cancer cells with the use of chemicals or other medications to interfere with the cancer cell's

ability to grow and multiply. Chemotherapy for leukaemia is given initially as remission induction, then as maintenance and as late intensification therapy. The most common routes for administering chemotherapy are oral, intramuscular, intrathecal, and intravenous. Intravenous chemotherapy is injected into a vein, using a needle and a cannula piercing through the skin. This allows rapid distribution of the chemotherapy throughout the body and is the most widely used method in children. Intravenous chemotherapy may be given as an injection straight into a vein or as an intravenous infusion or as a pump.

Procedure-related pain is a frequent and distressing component of medical care for children, their families and hospital staff. The aim of procedural pain management is to minimise physical discomfort, pain, movement and psychological disturbances without compromising patients' safety. Management may include analgesic agents via different routes of administration, concurrent sedation or general anaesthesia, and various non-pharmacological methods. The choice of technique will depend on the age and previous experience of the child, the type of procedure, the expected intensity and duration of pain, the treating environment and the health professional performing the procedure.

Intravenous cannulation is the most frequently used procedure in all the wards, casualty department and in preoperative preparation.Although health care professionals and adults often view venipuncture or Intravenous catheter insertion as quick, routine and relatively painless procedure,children consider the pain associated with such procedures as "clinically significant" and "distressing". It is a very painful and stressful procedure, thus emotions may become exaggerated at times, triggering vasovagal reaction. Patient's anxiety and fear concerning needles are real and may even prevent them from seeking health care.

Cryotherapy is usually called as cold application. Cold application is a simple and inexpensive therapy which has been accepted for decades as an effective non-pharmacologic intervention for pain management. Cryotherapy can be used to minimize the use of the drugs. It increases the pain threshold, decreases the inflammatory reaction and spasm. Cold application relieves pain by slowing the ability of pain fibres to transmit pain impulse.

Cold is commonly used in the treatment of acute soft tissue injuries and also has been shown to reduce pain effectively in the intravenous cannulation pain management. The proper use of cutaneous stimulation can reduce pain perception. Cutaneous stimulation can be performed by several methods such as simple rhythmic rubbing, use of pressure or electric vibrator, application of cold and hot at the site before injection, which has been significantly valued in various sites. Cold applications prevent the perception of pain through its effect on sensory nociceptors by decreasing the conduction time and synaptic activity in the peripheral nerves.

The gate control theory suggests that, cold applied directly over a vein can cause vasoconstriction; applying a cold pack proximal to the site of puncture will delay development of vasoconstriction for most patients. Placing the pack at least 15 seconds prior to sticking seems to increase pain relief, and placing the pack as close as possible to the site of puncture is helpful. The pack needs to be in place during the stick, so make sure it is out of the way of the zone to be prepped. Leaving the pack in place longer than 2-3 minutes may be distressing to the child and likely will not improve pain management.

1.1. NEED FOR THE STUDY

"The aim of the wise is not to secure pleasure but to avoid pain"

-Aristotle

Pain is a universal human experience and is a significant source of fear in most of the patients. For some it is a minor inconvenience and for others it is a major problem that causes suffering and reduces the quality of life. Pain is the commonest reason for seeking help from health care professionals.

Cancer patients often experience significant pain. Cancer pain is often chronic, persistent and prolonged and doesn't improve with time like the acute short-term pain. Cancer pain may also involve breakthrough pain, which is a sudden increase in intensity despite on-going control of the chronic pain. Pain in children with cancer is now recognized as a significant debilitating symptom that affects quality of life. Although advances in pain management have been made, there is still a need for improvement.

Worldwide, the annual number of new cases of childhood cancer exceeds 2, 00,000 and more than 80% are from the developing countries. In England only 0.5% of all cancer cases occur in children less than 15 years of age. In India however, it appears higher ranging from 1.6-4.8%. Leukemia is the most common childhood cancer in India between 25% and 40% out of which 60% to 85% reported are Acute Lymphoblastic Leukaemia.

As per the report of ***World Health Organization (2012)*** the incidence of childhood cancer in most populations in the world ranges from 75 to 150 per million children per year. The highest incidence is reported from Chennai and the lowest from rural Ahmedabad.The reported incidence in urban areas (Bangalore, Bhopal, Chennai, Delhi, Mumbai) is generally

higher than from rural areas (Barshi and Ahmedabad district) and more comparable with the average world incidence.

As per the annual statistical report of Institute of Child Health and Hospital for Children, Egmore (2012-2013) 103 new cases of Leukaemia with around 73 children with Acute Lymphocytic Leukaemia, 24 children with Acute Myeloctyic leukaemia and 6 children with Chronic Myeloctyic leukaemia were diagnosed and treated.

Pain inflicted by the insertion of large cannula into the vein is a significant cause of concern for both children and adults. Variouals non-pharmacologic strategies have been investigated and found to be highly effective in decreasing pain in children during intravenous cannulation

Cold therapy involves the application of either moist or dry cold to the skin. Dry cold can be applied by means of an ice, moist cold by means of towels soaked in ice water, cold hydro collator packs or immersion in a bath tub or under running cold water. Icing with ice cubes or blocks of ice made to resemble popsicles is another technique used for pain relief. Cold therapy is believed to be more effective than heat for variety of painful conditions. .

During clinical experience, the investigator witnessed the need for repeated intravenous cannulation for administering intravenous chemotherapy which was a painful and a distressing procedure for children with cancer. Thus the investigator was interested to emphasize on the pain relief measures by using topical ice pack application during intravenous cannulation. Although, topical ice pack application is easy and cost-effective, it is not practiced as a routine pain relief measure. With this intention, the investigator has taken steps to find the effectiveness of local cold application on pain response during intravenous cannulation in children who were receiving intravenous chemotherapy.

1.2. STATEMENT OF THE PROBLEM

A problem is an interrogative sentence or statement that asks what relationship exists between two are more variables

"A study to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy admitted in haematology ward, Institute of Child Health and Hospital for Children, Egmore, Chennai-08".

1.3. OBJECTIVES OF THE STUDY

A research objective is a clear, concise, declarative statement that provides direction to investigate the variables.

- To assess the intensity of pain during intravenous cannulation with routine care in children 5-12 years of age receiving intravenous chemotherapy in control group.
- To assess the intensity of pain during intravenous cannulation with ice pack application in children 5 -12 years of age receiving intravenous chemotherapy in experimental group.
- To compare the post-test level of pain between experimental and control group.
- To compare the effectiveness of ice pack application on pain reduction between experimental group and control group.
- To associate the effectiveness of ice pack application on the reduction of pain with the selected demographic variables in experimental group.

1.4. OPERATIONAL DEFINITION

The operational definition deals with the theoretical or the conceptual meaning of the variable under the study

- ***Effectiveness:*** In this study effectiveness refers to the reduction in the intensity of pain after ice pack application at the cannulation site prior to intravenous cannulation measured by Wong Baker's faces pain scale in school age children admitted in haematology ward.

- ***Cryotherapy:*** In this study cryotherapy refers to the application of ice pack, covered with a flannel cloth at the cannulation site for 15 seconds prior to intravenous cannulation.

- ***Topical anaesthetics:*** In this study topical anaesthetic refers to the ice pack applied peripherally as a pain relief measure at the cannulation site, prior to intravenous cannulation.

- ***Intravenous Cannulation:*** In this study intravenous cannulation refers to technique of placement of a cannula inside a vein in the child's hand for the purpose of giving chemotherapy drugs.

- ***Cannula:*** In this study cannula refers to a thin tube inserted into the vein in the child's hand for administrating chemotherapy drugs.

- ***Children:*** In this study children refers to the children between 5 - 12 years receiving intravenous chemotherapy admitted in the haematology ward.

- ***Chemotherapy:*** In this study chemotherapy refers to the drugs that are administered to treat children with leukaemia.

- ***Intravenous chemotherapy:*** In this study intravenous chemotherapy refers to the administration of anti-cancer drugs into the vein.

1.5. ASSUMPTION

Assumptions are principles those are accepted as being true based on logic or reasons, but without proof or verification

1) Intravenous cannulation is a routine painful procedure in children.

2) Topical ice pack application will reduce the intensity of pain during intravenous cannulation in children.

1.6. HYPOTHESIS

Hypothesis is a tentative prediction or explanation of the relationship between variables. It implies a systematic relationship between an independent and the dependant variable.

H_1 **:** The mean pain score of experimental group after ice pack application will be significantly lower than the mean pain score of control group.

H_2 **:** There will be significant association between pain score of children with selected demographic variables.

CHAPTER - II
REVIEW OF LITERATURE

Review of literature is one of the most important steps in the research process. A literature review is an account of the previous efforts and the achievements of the scholars and the researchers on a phenomenon. Literature review is the laborious task, but is essential if the research process is to be successful.

The literature for this study is divided into two parts

2.1. PART I: LITERATURE ON INTRAVENOUS CANNULATION AND CRYOTHERAPY

1) Literature related to Intravenous cannulation and Pain

2) Literature related to Intravenous chemotherapy

3) Literature related to cryotherapy and pain management

2.2. PART II: CONCEPTUAL FRAME WORK

2.1 Part I : Literature on Intravenous Cannulation and Cryotherapy

2.1.1 Literature Related to Intravenous Cannulation and Pain

Kennedy RM, Janelluhmann, ZempskyW., (2008) conducted an observational and self – report survey analysis on clinical implication of unmanaged needle insertion pain among 171 children between 3 to 17 years of age who underwent a routine venipuncture by using visual analogue scale. The results were 36% of the children at the age of 3 to 6 years and 13% of children 7 to 17 years of age reported moderate to severe pain. So the study concluded that pain from venipuncture and intravenous cannulation as an important source of paediatric pain.

Vihunen R. Sihvonen., (2005) conducted a study, in 80 children between 3-8 years on the assessment and management of pain after IV cannulation in two otological wards. The groups were compared with each other; on one ward nurse used Faces scale in children's self-assessment of pain while the other was a comparative ward. The study revealed that 40%of children had severe or intolerable pain after IV cannulation.

Desiree Lie., (2002) conducted a study on the measures in minimizing needle pain in children. The survey suggested that venipuncture as a source of pain considerable distress among children. The study suggested that 34% to 64% of children experience stress of pain from the procedure and 50% of children report needle stick experiences as unpleasant and painful.

Marion E. Broom., (2000) conducted a study on the medical fears, coping behaviour pattern and pain perception in 17 children during painful procedures. This study explored that majority of the children perceived a great deal of pain during the painful procedures. The study implied the need for continual preparation and support of children during painful procedures.

Goodenough TB, Perrott DA et al., (2000) conducted a study on the parental assessment of child's behavioural reaction on the intensity of needle pain during routine venepuncture, in 88 children of 3-12 years of age by using Faces Pain Scale. The study concluded that those children who reported venipuncture as **"*hurting more*"** also gave the highest mean needle pain ratings and tended to have their pain under predicted by their parents.

Lander J, Hodgins M, Fowler-Kerry S., (1992) conducted a cross-sectional descriptive study to explore expected, experienced and recalled pain, and anxiety in 138 children of 5-17 years of age during

venipuncture by using visual analogue scale. The study revealed that following venipuncture, majority of the children reported sensory and affective pain.

Literature Related To Intravenous Chemotherapy

Chen YJ, Wu CS, et al., (2012) conducted a study on the effect of Baicalein on the enhancement of anti-leukaemia effect of Vincristine in childhood Acute Lymphoblastic Leukaemia. The results demonstrated that baicalein an active flavonoid with anti-cancer, anti-inflammatory, and anti-allergic property has been recommended for future clinical trials in the treatment of paediatric leukaemia owing to baicalein's beneficial effects in alleviating the vomiting, nausea, and skin rashes caused by chemotherapy.

Hijiya N,Barry E, Arceci RJ., (2012) conducted a study on the effect Clofarabine in pediatric acute leukemia, stated that Clofarabine a second-generation purine nucleoside analogue has significant anti-leukemic activity .It is approved by the United States Food and Drug Administration (FDA) for the treatment of relapsed or refractory Acute Lymphoblastic Leukemia in children. Combinations of clofarabine with other purine nucleoside analogues or DNA-damaging agents have been investigated and now been advised in the treatment of paediatric Acute Lymphoblastic Leukemia(ALL).

Escherich G, Zimmermann M,et al., (2012) conducted a study to compare the therapeutic effects of two anthracycline drugs , daunorubicin (DNR) and doxorubicin (DOX). in 743 samples by randomization :247 to the DOX; 252 to the DNR 30 mg/m(2) ; and DNR to the 40 mg/m(2) arm. The study concluded that single dose daunorubicin 30 or 40 mg/m(2) is similar to that of doxorubicin given in a dose of 30 mg/m(2).

Csordas K, Hegyi M et al (2013), conducted a comparative study on the pharmacokinetics and toxicity of methotrexate (MTX) and 7-hydroxy-methotrexate (7-OH-MTX) in 65 children between age groups 6-14 years. The study revealed that toxicity occurred more frequently in children aged older than 14 years. The study concluded that monitoring of pharmacokinetics is essential to prevent the development of severe adverse events in adolescents.

2.1.3. LITERATURE RELATED TO CRYOTHERAPY AND PAIN MANAGEMENT

A comparative study by Children's Hospital of Philadelphia., (2012) conducted in children between 4 to12 years to test the effectiveness of Buzzy®, a battery-powered reusable device that provides cold and vibration with topical Lidocaine cream in reducing the pain associated with intravenous cannulation revealed that Buzzy® provides a potential alternative to treating paediatric intravenous cannulation pain in the emergency department (ED), as cold and vibration are quick-acting options for pain relief.

Crowley MA, Storer A, et al., (2011) in association with US Department of Health Services, conducted a study on the Needle- related procedural pain and reduction of distress in paediatric patients in the emergency department. Five interventions as Bio-behavioral interventions, Dermal anaesthetic preparations, Sub-dermal local anaesthetic with needle-free delivery, Local application of ice and Pacifiers and sucrose were graded based on Melnyk & Fineout-Overholt grading system as Level A High (beneficial), Level B Moderate (is likely to be beneficial), Level C Weak (limited or unknown effectiveness) or Not recommended for practice .The result of the study supported the use of local application of ice graded as Level B, moderate in the reduction of pain and distress associated with venepuncture.

Farhadi and M. Esmailzadeh., (2011), conducted a study to assess the effectiveness of local cold during intramuscular injection of penicillin Benzathin. In this study 60 patients were taken and divided into case and control group using a randomized location sampling. In case group, local cold (ice) was used 30 s before IM injection while in control group, routine IM injections were given. Data was collected using questionnaire and visual analog scale (VAS). Data were analyzed with T- test. Results showed that local cold significantly decreased the severity of pain due to penicillin benzathin IM injection in case group as compared with control group.

Amy L.Baxter ,Lindsey.L.Cohen and et al., (2011) conducted a study in 81 children of 4-18 years with the integration of vibration and topical cold in experimental group(40) and vapocoolant spray in the control group(41) and pain being assessed by using Wong Baker's faces pain scale. The study concluded that cold vibrators significantly reduced pain without compromising the procedure.

Allred K. D., (2010), conducted a quasi-experimental study to compare the effectiveness between ice and towel (moist cryotherapy) and ice pack (dry therapy) in IV cannulated patients assigned in two groups. Group I received ice towels whereas Group II used ice pack to reduce pain in IV cannulation site delivered each for duration of 10 minutes. The study results concluded that both moist and dry cryotherapy reduced pain during in IV cannulated patients.

Aminabadi NA, Farahani RM., (2009) conducted a study in 160 children aged 5-6 years selected on a random basis, the subjects were allocated to the without ice pretreatment (WIP) group (topical anesthesia + counter stimulation + distraction) or the ice pretreatment (IP) group (cooling + topical anesthesia + counter stimulation + distraction) during the administration of an inferior alveolar nerve block. The children's

behavior was assessed using the sound, eye, and motor (SEM) scale. The study concluded that cooling the site prior to the injection significantly reduced the pain.

Mahajan S, et al., (2008) conducted a study to determine the effectiveness of cryotherapy on arteriovenous fistula puncture pain in 60 hemodialysis patients (30 in experimental and 30 in control group) assessed using randomized control trial. The objective and subjective pain scoring performed on two consecutive days of hemodialysis revealed that the objective and subjective pain scores were significantly (p=0.001) reduced within the treatment group. Results revealed that cryotherapy was effective in reducing arterivenous fistula puncture pain in hemodialysis patients.

Leahy S, Kennedy RM, Hesselgrave J, et al., (2008) described that Venipuncture and intravenous cannulation are among the most common and widespread medical procedures performed on children today. This study stressed upon the importance of a multidisciplinary evidence-based approach; a system-wide protocol for the administration of local anaesthetics; convenient access to topical local anaesthetics; department and hospital-wide support for educational efforts, including training in non-pharmacologic techniques used by child life specialists during venipuncture.

Ali Fakhr Movahedi , Mahvash Salsali et al., (2006) conducted a study to assess the effect of local refrigeration prior to venipuncture. Eighty children between 6-12 years were selected and divided into two groups as test group and control group. In test group injection site was refrigerated for 3 minute using ice bag before injection and in control group it was performed according to normal routine. By using CHEOPS (Children's Hospital of Eastern Ontario Pain Scale), oucher's scale, and with physiological and behavioural responses, it was found that average

pain intensity in local refrigeration is much less compared to pain intensity in control group. The results of this study suggest that the use of local refrigeration prior to venipuncture can be considered an easy and effective intervention of reducing venipuncture-related pain.

Ebner CA., (1996) conducted a quasi- experimental study to determine, whether cold therapy decrease the perceived pain associated with IM injection in children. Sample of 40 children with age 10 to 18 years were randomly assigned to control and experimental group. The experimental group had an ice pack placed on the injection site for 15 minutes prior to injection and control group with normal routine care. Children who receive cold therapy showed significant reduction in IM injection pain.

Karen Abbott, Susan Fowler-Kerry., (1995) conducted a double blind study to find out the efficiency of refrigerant topical anaesthetic in reducing injection pain in preschool children experiencing routine DPT Immunization on a sample of 90 subjects aged 4-5 1/2 years, who were randomly assigned to one of three groups;(a)refrigerant topical anaesthetic;(b)placebo topical spray and;(c)control. Pain was subjectively measured using a four –point visual analogue scale. Both the refrigerant topical anaesthetic spray and the placebo spray significantly reduced injection pain. The results of the study supported the use of an intervention, such as refrigerant topical anaesthetic, as a practical, simple, and effective treatment strategy for reduction of short-term painful procedures like injections.

Ernst E, Fialka V., (1994) conducted a study to determine the clinical effectiveness of analgesic cold therapy concluded that ice has a strong short-term analgesic effect in many painful conditions. The mechanisms by which cryotherapy might elevate pain threshold include an antinociceptive effect on the gate control system, a decrease in nerve conduction, reduction in muscle spasms, and prevention of edema after injury.

2.2. PART-II: CONEPTUAL FRAME WORK

The framework is a brief explanation of the theory or those portions of a theory that are to be tested in a quantitative study. Conceptual framework presents the logically constructed concepts of the research study. Conceptual framework is usually constructed by using the researcher's own experience.

The conceptual frame work of this study was derived from the ***Roy's Adaptation Theory*** depicted by ***Sr.Callista Roy.*** This theory is concerned with the focus, target and the nursing care indicated.

In this study the investigator has concerned the following as

- ***Focus :*** Intensity of pain perceived during intravenous cannulation.
- ***Target :*** Reduction of pain during intravenous cannulation
- ***Nursing care :*** Application of ice pack prior to intravenous cannulation.

In this system input, throughout and output is used.

The person is an open adaptive system with (input), who adapts by processes or the coping mechanisms (throughput) resulting in either adaptive responses or ineffective responses (output).

INPUT

Input is identified as stimuli that can come from the environment or from within the person and the person's adaptation level. The stimuli can be focal (immediately confronting), contextual (all the other stimuli that are present) and residual (non-specific such as attitudes about illness)

The investigator identified the stimuli as

1) ***Focal*** **-** Intravenous cannulation, Ice pack application

2) ***Contextual*** **-** Treatment room

3) ***Residual*** **-** Thoughts of pain perception

THROUGHPUT

Throughput makes use of an individual's processes and effectors.

Processes refer to the control mechanisms that a person uses an adaptive system.

The investigator identified that the coping mechanism of the child was based on the attachment and bondage of the child with the care givers, care givers support and reassurance to the child, h/o previous experience of intravenous chemotherapy.

Effectors refer to the physiologic reactions, self-concept, role function and interdependence involved in adaptation.

The investigator identified the following as the effectors

Physiological function : Perception of pain

Physiological reactions:

- withdrawing the hand
- crying
- moaning
- Restlessness
- Agitation

Self-concept : All the children normally feel that injections are painful

Role function : Lack of normal peer group activities.

Interdependence : Dependant on the care givers.

The investigator intervened the following as the indicated nursing actions

Experimental group: Topical ice pack application prior to intravenous cannulation

Control group: Routine care during intravenous cannulation.

OUTPUT

Output is the outcome of the system, when the system is a person. It refers to the person's behaviour.

In this study it denotes the child's facial reaction to pain during intravenous cannulation. In the output, the assessment of pain is performed by using Wong Baker's Faces pain assessment scale. Faces scale consists of a number of 6 cartoon type faces in which the facial expression varies on one end with either a smiling face or a neutral (no pain) face to an expression which signifies extreme pain.

The maximum total score is 10 with points ranging from 0 to 10

0 – No hurts

2 – Hurts little bit

4 – Hurts little more

6 – Hurts even more

8 – Hurts whole lot

10 – Hurts worst

Based on the scores obtained the intensity of pain is categorized as

0 – No pain

1-2 – Mild

3-6 – Moderate

7-10 – Severe

The investigator identified that there was persistence of pain (severe) in the control group and reduction of pain (mild and moderate) in the experimental group.

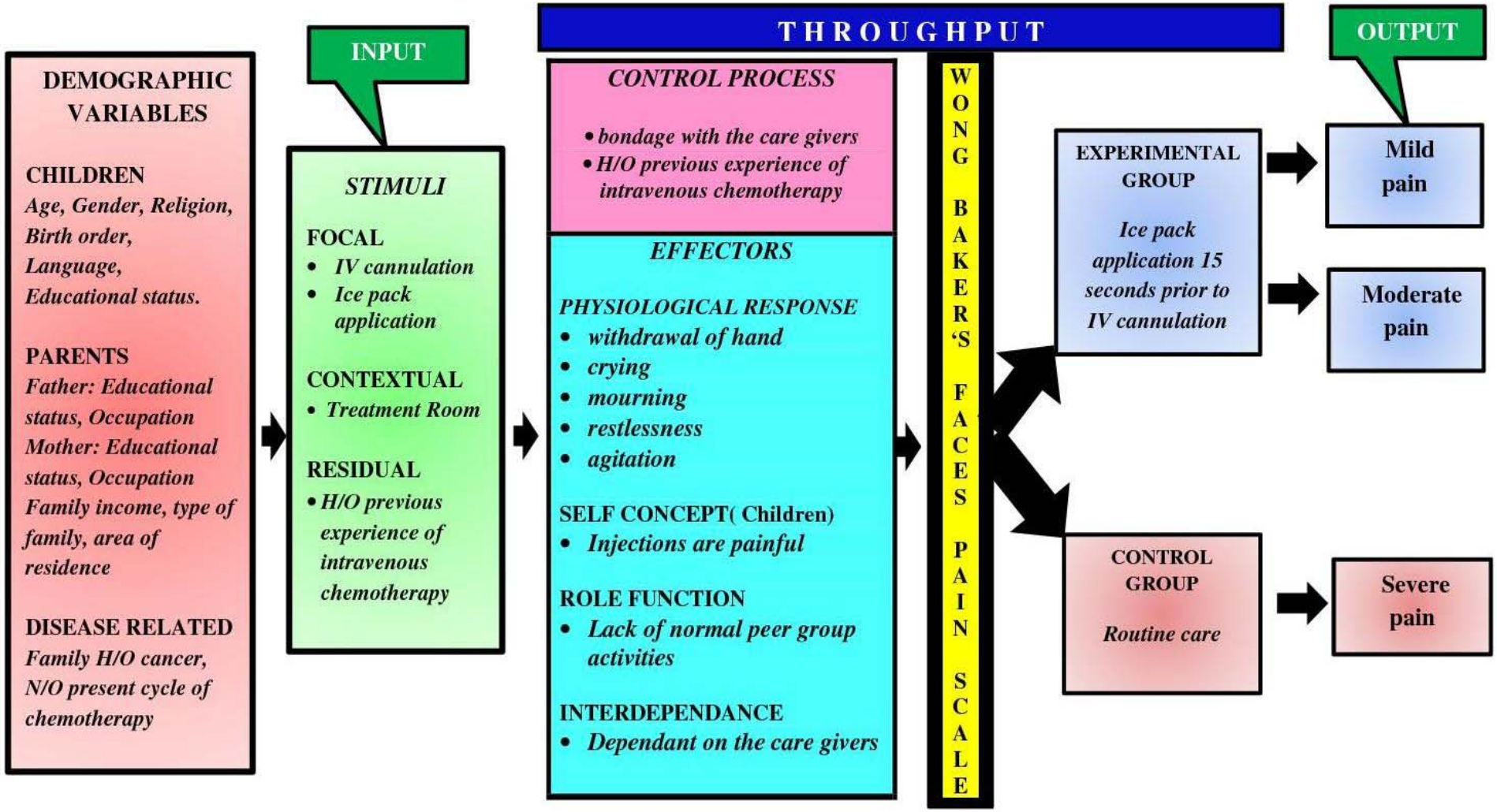


Figure 1: CONCEPTUAL FRAMEWORK BASED ON MODIFIED ROY'S ADAPTATION MODEL

CHAPTER – III
METHODOLOGY

This chapter deals with the methodology to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy admitted in haematology ward, Institute of Child Health and Hospital for Children, Egmore, Chennai-08.

Research methodology includes the research design, variables of the study, setting, population, sample, criteria for sample selection, sampling techniques, sample size, development and the description of the tool, scoring, content validity, pilot study, reliability, plan for the data collection and analysis.

3.1. RESEARCH APPROACH

The research approach used in the study is ***Quantitative approach.***

3.2. RESEARCH DESIGN

The research design is the master plan specifying the methods and procedures for collecting and analysing the needed information in the research study

The research design used in the study is ***True Experimental Post - test only control group design***

E	X	O1
C	-	O2

Key

E – Experimental group
C – Control group
X – Interventions (ice pack application)
O1 – Observation on the experimental group
O2 – Observation on the control group

3.3. RESEARCH VARIABLES

Research variables are the attributes, qualities, properties, characteristics that are observed or measured in a natural setting without manipulation and establishing cause-and-effect relationship.

- ***Independent variable*** **-** Ice pack application
- ***Dependant variable*** **-** Pain during intravenous cannulation

3.4. RESEARCH SETTING

The research setting was the location in which the research is conducted.

The study was conducted at the ***haematology ward, Institute Of Child Health and Hospital for Children, Egmore, Chennai-08.***

3.5. STUDY POPULATION

The study population is the entire set of individuals or objects having some common characteristics selected for the research study.

The study population for the study is the ***children, 5-12 years of age who were receiving intravenous chemotherapy admitted in haematology ward.***

3.6. SAMPLING TECHNIQUE

Sampling is the process of selecting representative units from the entire population of study

The sampling technique used in the study was ***Simple Random Sampling***- every member of the population had an equal chance of being selected as subject.

3.7. SAMPLE

Sample is the representative unit of a target population.

The study sample comprised of children 5-12 years of age who received intravenous chemotherapy at Haematology Department, Institute of Child Health and Hospital for Children, Egmore, Chennai-08"

3.8. SAMPLE SIZE

The sample size was ***60 children (30 experimental group, 30 control group)*** between age groups 5-12 years who received intravenous chemotherapy at Haematology Department, Institute of Child Health, and Hospital for Children, Egmore, Chennai-08".

3.9. SAMPLING CRITERIA

Inclusion criteria

- Children of age group 5-12 years.
- Children who were receiving intravenous chemotherapy.
- Children admitted in haematology ward.
- Children willing to participate in the study.

Exclusion criteria

- Children less than 5 years of age.
- Children with bleeding disorder
- Children didn't receiving intravenous cannulation.
- Children with skin lesions and rashes.

3.10. DEVELOPMENT OF THE DATA COLLECTION INSTRUMENT

The data collection instrument is a tool used by the researcher to find the effect on selected variables in the study.

The steps used for the development of tool for this study were as follows

1) Appropriate tool was selected with the help of review of literature

2) Direct assessments of the clients were performed during the clinical postings

3) Obtained expert opinion from Haematology and Nursing Departments

4) Construction of tools

5) Content validity

6) Pre-testing of the tool

7) Checking the reliability of the tool

3.11 DESCRIPTION OF THE TOOL

A Structured Interview Schedule and the Wong Baker's Faces Pain Scale are used for observing the samples

The tool consists of two sections

SECTION A

This section deals with demographic details of children, parents and cancer related information.

1) ***Demographic information of Children:*** Age, Gender, religion, Birth Order, Language and Child's Education.

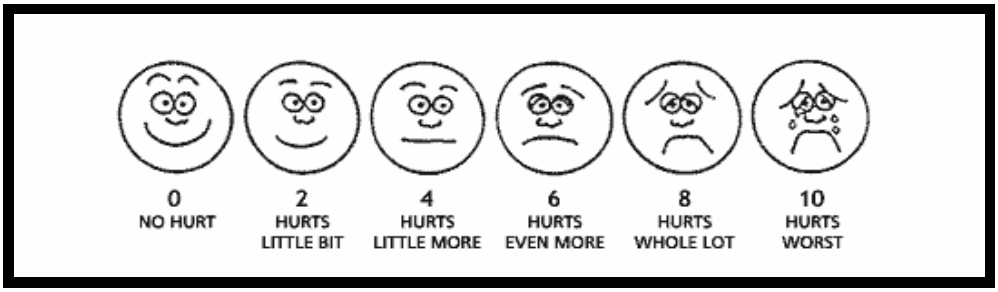
2) ***Demographic information of Parents:*** Father's Education, Mother's Education, Father's Occupation, Mother's Occupation, Family Income, Type of Family and Area of Residence.

3) ***Disease related information:*** Family history of Cancer, Number of Chemotherapy Cycles.

PART B

Deals with ***Wong Baker's faces pain rating scale.*** Faces scale consists of a number of 6 cartoon type faces in which the facial expression varies on one end with either a smiling face or a neutral (no pain) face to an expression which signifies extreme pain. Face pain scales are suitable for children who are at a developmental age of 5 years or above.

Wong –Baker Faces Pain Rating Scale



3.12. ETHICAL CONSIDERATION

The study was conducted after getting the approval and ethical clearance from the Institutional Ethical Committee, Madras Medical College, Chennai-03. The investigator was instructed to follow the guidelines of the ethical committee.

3.13 TESTING OF THE TOOL

Validity

The content validity was obtained from Haematology HOD, Institute of Child Health and two Child Health Nursing experts. Experts' suggestions are incorporated in the tool. Validity of the tool was assessed using content validity. Content validity was determined by experts from nursing and medical fields.

3.14 PILOT STUDY

A formal permission was obtained from the Professor and the Head of the Department of Haematology, Institute of Child Health and Hospital for Children, Egmore, Chennai-08. The Pilot study was conducted at the Haematology inpatient Department.

The result showed co-relation between cryotherapy (ice pack application) and intravenous cannulation. The study was reliable and practically feasible to proceed for the main study.

Reliability

The accuracy and consistency of the research tool is called as reliability. After pilot study the reliability of the tool was assessed using inter-rater method. The correlation coefficient value was 0.87. This correlation coefficient was very high and was found to be a good tool for assessing the effectiveness of cryotherapy in children during intravenous cannulation and was also found to be cheap and practically feasible to proceed with the main study.

3.15. PLAN FOR DATA ANALYSIS

Data collected were analysed through descriptive statistics as mean and inferential statistics as Independent “t” test, Chi-Square Test.

Statistical analysis

- Demographic variables in categories were in frequencies with their percentages.
- Post-test level of pain scores in the experimental and control groups were given in percentages
- Post –test level of pain between experimental and control group were compared using Chi-square test

- Post –test level of pain score between experimental and control group were compared using student independent “t” test
- Differences between reduction of pain between experimental and control group were analysed using proportion with 95% CI and mean difference of 95% CI
- Association between demographic variables and post-test level of pain score in experimental group were analysed using student Chi-square test.
- Simple bar diagram, pie diagram, pyramid diagrams were used to represent the data.

3.16. PROCEDURE FOR DATA COLLECTION

A formal permission was obtained from the Professor and the Head of the Department of Haematology, Institute of Child Health and Hospital for Children, Egmore, Chennai-08.

The severity of pain during intravenous cannulation in children receiving chemotherapy with cryotherapy (ice pack application) and routine care during intravenous cannulation were assessed using Wong Baker’s faces pain rating scale.

Rapport was established after a brief introduction about the study and its purpose. Topical ice pack application at the cannulation site was performed after getting consent from the parents of the patients. The investigator followed all the ethical principles for collecting the data.

PROCEDURE

1) Established rapport with the child and the parents.

2) Eplained the procedure to the child and the parents and obtained the informed consent from the parents.

3) Washed and dried up the hands.

4) Placed the child in the comfortable position (supine position)

5) Prepared the ice pack ((ice cubes sprinkled with a pinch of salt in a 5X5 centimeter plastic cover wrapped with 10X10centimeters flannel cloth).

6) Selected the vein for intravenous cannulation in the child's hand.

7) Applied ice pack in the arm 5 centimeters proximal to the cannulation site 15 seconds followed by intravenous cannulation.

8) Assessed the pain response of the child by using Wong Baker's faces pain scale.

9) The findings were documented for data analysis

10) Total duration for the procedure was around 10 minutes.

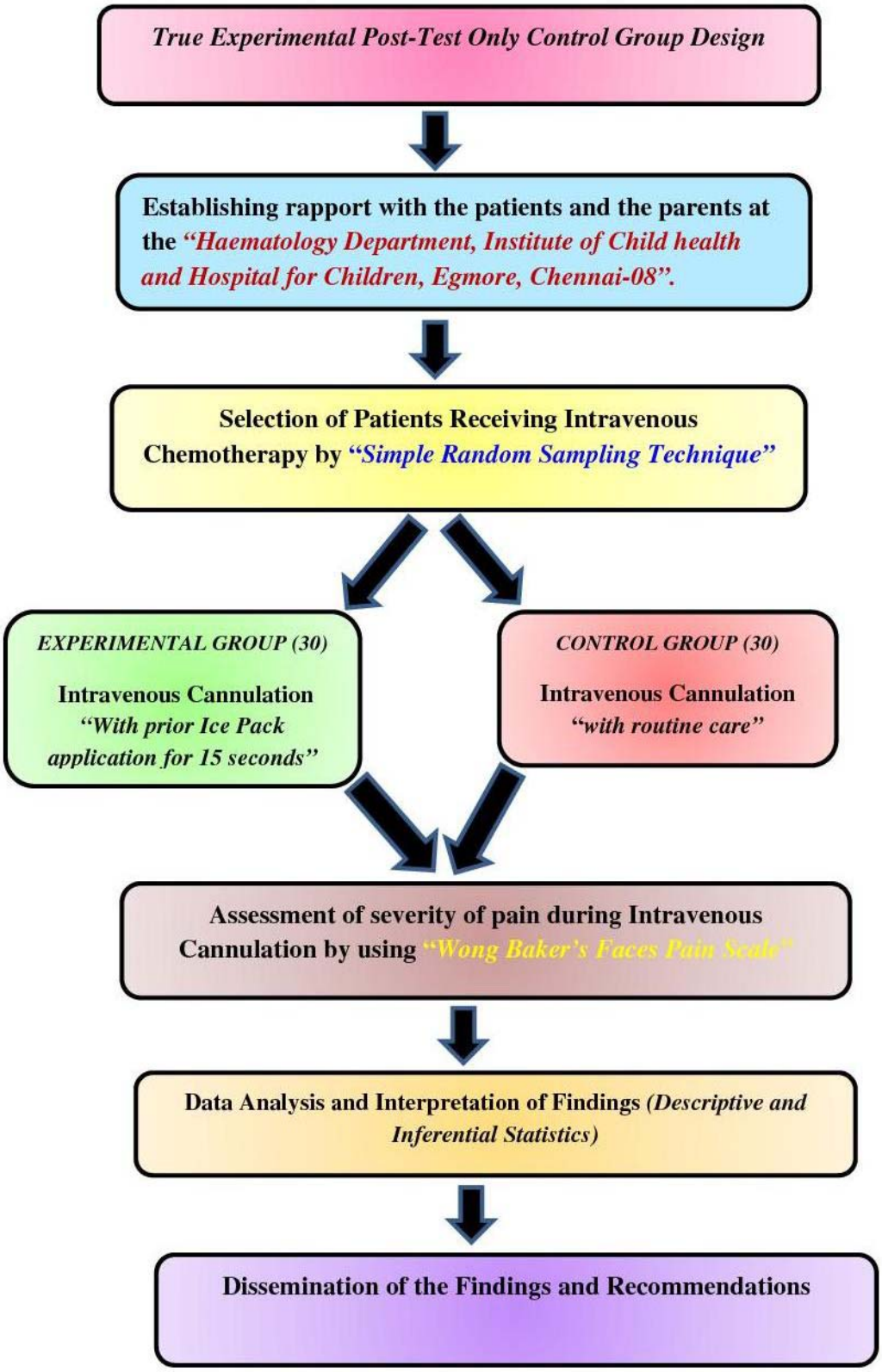


FIGURE 2: SCHEMATIC REPRESENTATION OF THE STUDY

CHAPTER - IV
ANALYSIS AND INTERPRETATION OF DATA

Analysis is the method for rendering quantitative meaningful and providing intelligible information, so that the research problem can be studied and tested including the relationship between the variables.

This chapter deals with analysis and interpretation of data collected from 60 children, between 5-12 years and from their parents. The data collected deals with the demographic information's and the level of pain experienced by the children 5-12 years of age receiving intravenous chemotherapy in the Haematology ward, Institute of Child Health and Hospital for Children, Egmore, Chennai-08.

The data were assembled, analysed, tested for their significance and tabulated according to the objective under the following headings.

ORGANIZATION OF DATA

Section-A : Description of the demographic data of children and their parents who participated in the study.

Section-B : Description of Post –Test level of pain in control group.

Section -C : Description of Post –Test level of pain in experimental group .

Section-D : Comparison of the level of pain and the effectiveness of ice pack application between experimental and control group.

Section-E : Association of post-test pain score with selected demographic variables of experimental group.

SECTION A

Table -4.1.1 : Children Demographic Information
Percentage Distribution of Demographic Data of children (N = 60)

S. No	Demographic Variables		Group			
			Experimental		Control	
			Number	Percentage	Number	Percentage
	Age	5 -6 years	5	16.7%	5	16.7%
		6 -8 years	6	20.0%	11	36.7%
		8 -10 years	11	36.7%	6	20.0%
		10-12 years	8	26.7%	8	26.7%
	Gender	Male	21	70.0%	19	63.3%
		Female	9	30.0%	11	36.7%
	Religion	Hindu	26	86.7%	27	90.0%
		Muslim	3	10.0%	2	6.7%
		Christian	1	3.3%	1	3.3%
	Birth order	One	11	36.7%	14	46.7%
		Two	14	46.7%	14	46.7%
		Three	5	16.7%	2	6.7%
	Language	Tamil	26	86.7%	27	90.0%
		Telugu	2	6.7%	2	6.7%
		Hindi	2	6.7%	1	3.3%
	Child's education	Primary	22	73.3%	24	80.0%
		Secondary	8	26.7%	6	20.0%

The above table describes about the demographic data of children 5-12 years of age who were receiving intravenous chemotherapy.

With regard to age it was seen that 11(36.7%) fell between the age groups 8-10 years, 8(26.7%) between the age groups 10-12 years, 6(20.0%) between the age groups 5(16.7%) between the age groups 5-6 years in experimental group.

In the control group11 (36.7%) fell between the age groups 6-8 years, 8(26.7%) belong to the age groups10-12 years, 6(20.0%) between the age groups 8-10 years and 5(16.7%) between the age groups 5-6 years. .

With respect to gender 21(70%) are male and 9(30%) are female children in the experimental group .There were 19(63.3%) as male and 11(36.7%) as female children in the control group.

In relation to religion 26(86.7%) were Hindus, 3(10.0%) were Muslims and 1(3.3%) were Christians belonging to experimental group. In control group 27 (90.0%) were Hindus, 2(6.7%) were Muslims and 1(3.3%) were Christians.

With regard to the birth order of the children in the experimental group 14(46.7%) were born as second, 11(36.7%) as first and 5(16.7%) as third child for their parents. In the control group 14(46.7%) were born as first, 14(46.7%) as second and 2(6.7%) as third for their parents.

Considering the language of the children in experimental group majority of the children 26(86.7%) belongs to Tamil, 2(6.7%) Telugu and 2(6.7%) Hindi. In the control group 27(90%) were from Tamil, 2(6.7%) from Telugu and 1(3.3%) from Hindi.

Regarding the educational status most of the children 22(73.3%) were studying primary school education and 8(26.7%) were studying secondary school education in the experimental group. In the control group 24(80%) children were doing their primary school education and 6(20%) were doing their secondary school education.

Table -4.1.2: Parents Demographic Information
Percentage Distribution of Demographic Data Parents (N = 60)

Demographic Variables		Group			
		Experimental		Control	
		Number	Percentage	Number	Percentage
Father's education	Uneducated	3	10.0%	3	10.0%
	Primary	9	30.0%	7	23.3%
	Secondary	16	53.3%	18	60.0%
	Graduate	2	6.7%	2	6.7%
Mother's education	Uneducated	5	16.7%	4	13.3%
	Primary	12	40.0%	9	30.0%
	Secondary	11	36.7%	15	50.0%
	Graduate	2	6.7%	2	6.7%
Father's occupation	Labourer	10	33.3%	5	16.7%
	Self employed	10	33.3%	14	46.7%
	Private	9	30.0%	10	33.3%
	Government	1	3.3%	1	3.3%
Mother's occupation	Housewife	23	76.7%	25	83.3%
	Self employed	5	16.7%	3	10.0%
	Private	2	6.7%	2	6.7%
Family Income	Rs.3000 - 5000	15	50.0%	10	33.3%
	Rs.5001 - 7000	12	40.0%	15	50.0%
	Rs.7001 - 9000	3	10.0%	5	16.7%
Type of family	Nuclear family	27	90.0%	25	83.3%
	Joint family	3	10.0%	5	16.7%
Area of residence	Rural	14	46.7%	9	30.0%
	Urban	12	40.0%	14	46.7%
	semi urban	4	13.3%	7	23.3%

The above table describes the demographic information of the parents who participated in the study

In consideration with the father's educational status in the experimental group about 16(53.3%) studied upto secondary education. In the control group 18(60.0%) completed secondary education.

With regard to the mother's educational status in the experimental group 12(40.0%) studied upto Primary school education. In the control group 15(50%) of mothers have completed their secondary school education.

With respect to the father's occupation in the experimental group most of them were as10 (33.3%) labourers. In the control group majority of the fathers14 (46.7%) were self-employed

With respect to the mother's occupation in the experimental group majority of the mothers 23(76.7%) were as house-wives. In the control group 25(83.3%) were as housewives,

Regarding the income of the family in the experimental group 15(50%) was between the range Rs 3000-Rs 5000. In the control group majority 15(50%) was within the range of Rs 5001-Rs 7000.

Considering the type of family in the experimental group majority 27(90%) were nuclear families and 3(10.0%) were as joint families. In the control group 25(83.3%) belongs to nuclear family and the remaining 5(16.7%) belongs to joint family.

With regard to the area of residence majority in the experimental group 14(46.7%) reside in rural area, 12(40.0%) in urban area and 4(13.3%) in semi-urban area. In the control group about 14(46.7%) reside in urban area, 9(30.0%) in rural area and 7(23.3%) reside in semi-urban area.

Table -4.1.3: Disease Related Information
Percentage Distribution of disease related information (N = 60)

Cancer Details		Group			
		Experimental		Control	
		Number	Percentage	Number	Percentage
Family H/O cancer	No	29	96.7%	28	93.3%
	Yes	1	3.3%	2	6.7%
Chemotherapy cycle	First cycle	4	13.3%	3	10.0%
	Second cycle	11	36.7%	9	30.0%
	Third cycle	8	26.7%	8	26.7%
	> Third cycle	7	23.3%	10	33.3%

The above table describes the family history of cancer and the number of chemotherapy cycles received by the children.

Regarding the family history of cancer in the experimental group majority 29(96.7%) there was no incidence of cancer in their families and only 1(3.3%) there was an incidence of cancer in their family. In the control group 28(93.3%) there was no incidence of cancer in their families and 2(6.7%) there was an incidence of cancer in their family.

Among 30 children in the experimental group majority 11(36.7%) had come for second chemo cycle, 8(26.7%) for third chemo cycle, 7(23.3%) were receiving more than three cycles of chemotherapy and only 4(13.3%) had come for first cycle of chemotherapy. In the control group about 10(33.3%) were receiving more than three cycles of chemotherapy, 9(30.0%) had come for second chemo cycle, 8(26.7%) were for third chemo cycle and only 3(10.0%) had come for the first cycle of chemotherapy.

Figure 3: Demographic Variable - Age Distribution of Child

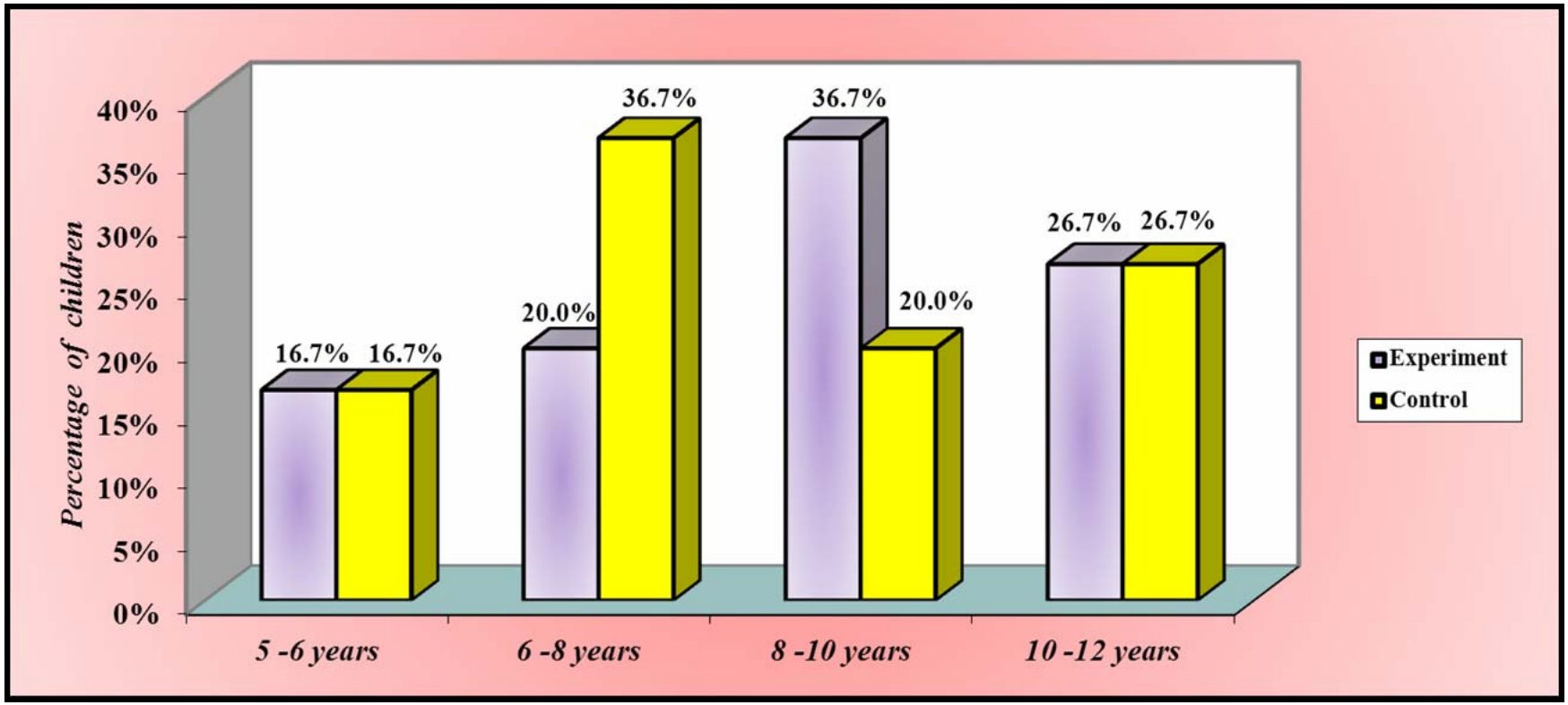


Figure 3 shows that majority of children are between the age group 6-8 years (36.7%) in experimental group and (36.7%) between the age group 8-10 years in control group.

Figure 4: Demographic Variable- Sex Distribution Of Child

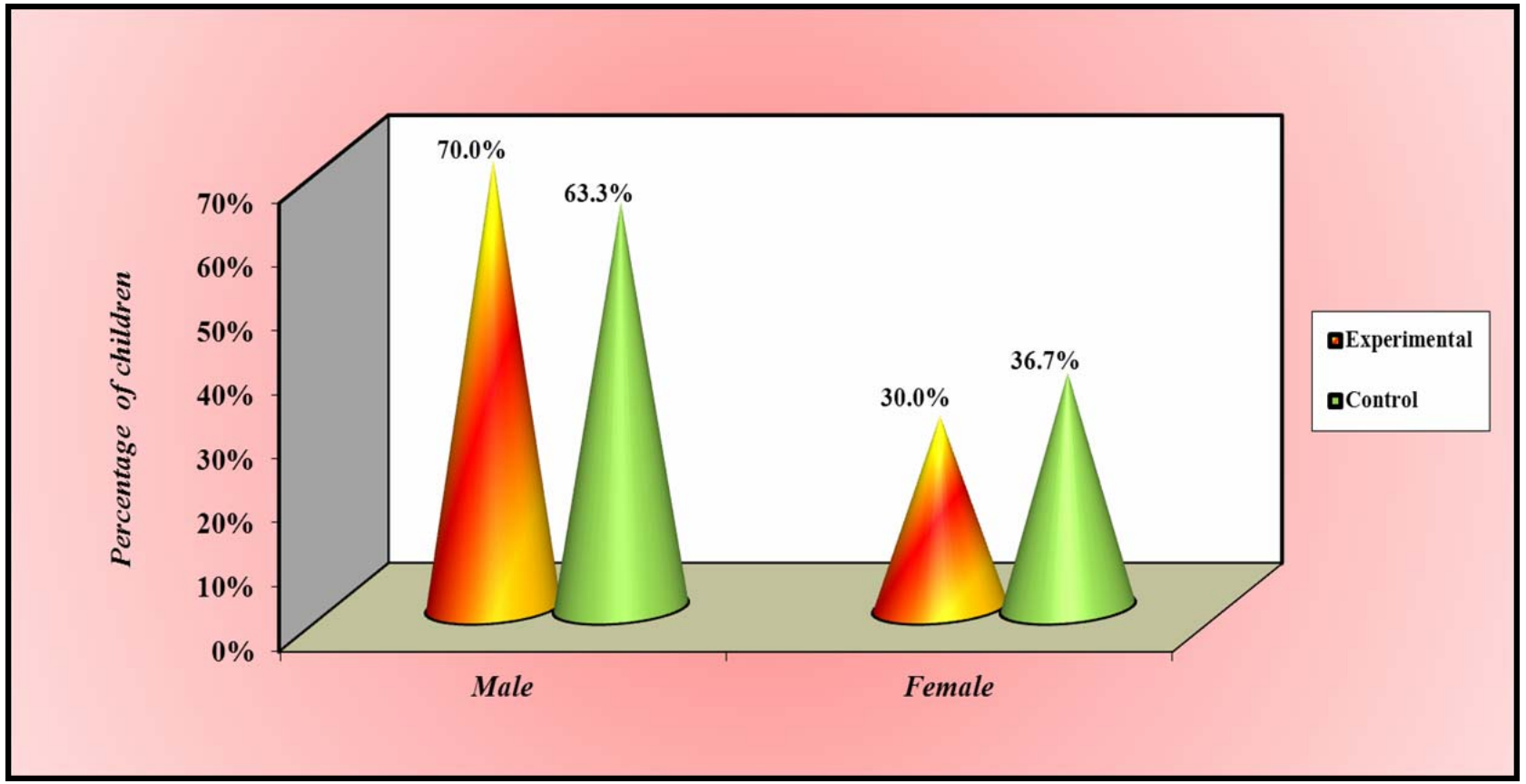


Figure 4 shows that majority of children were male (70%) in experimental group and (63.3%) in control group.

Figure 5: Demographic Variable - Religion of Child

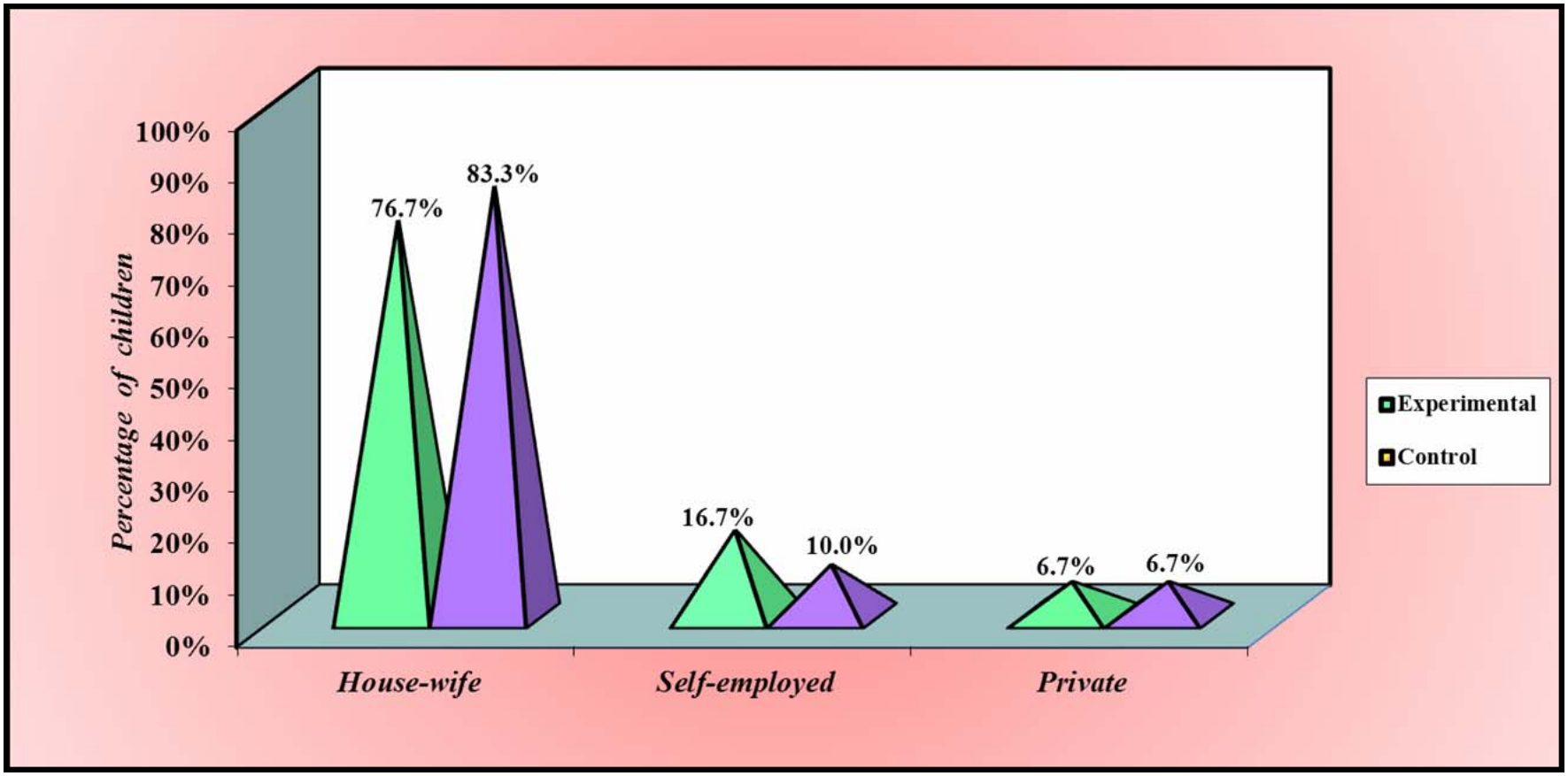


Figure 5 shows that majority of children were Hindus (88.7%) in experimental group and (90%) in control group

Figure 6: Demographic Variable - Birth Order of Child

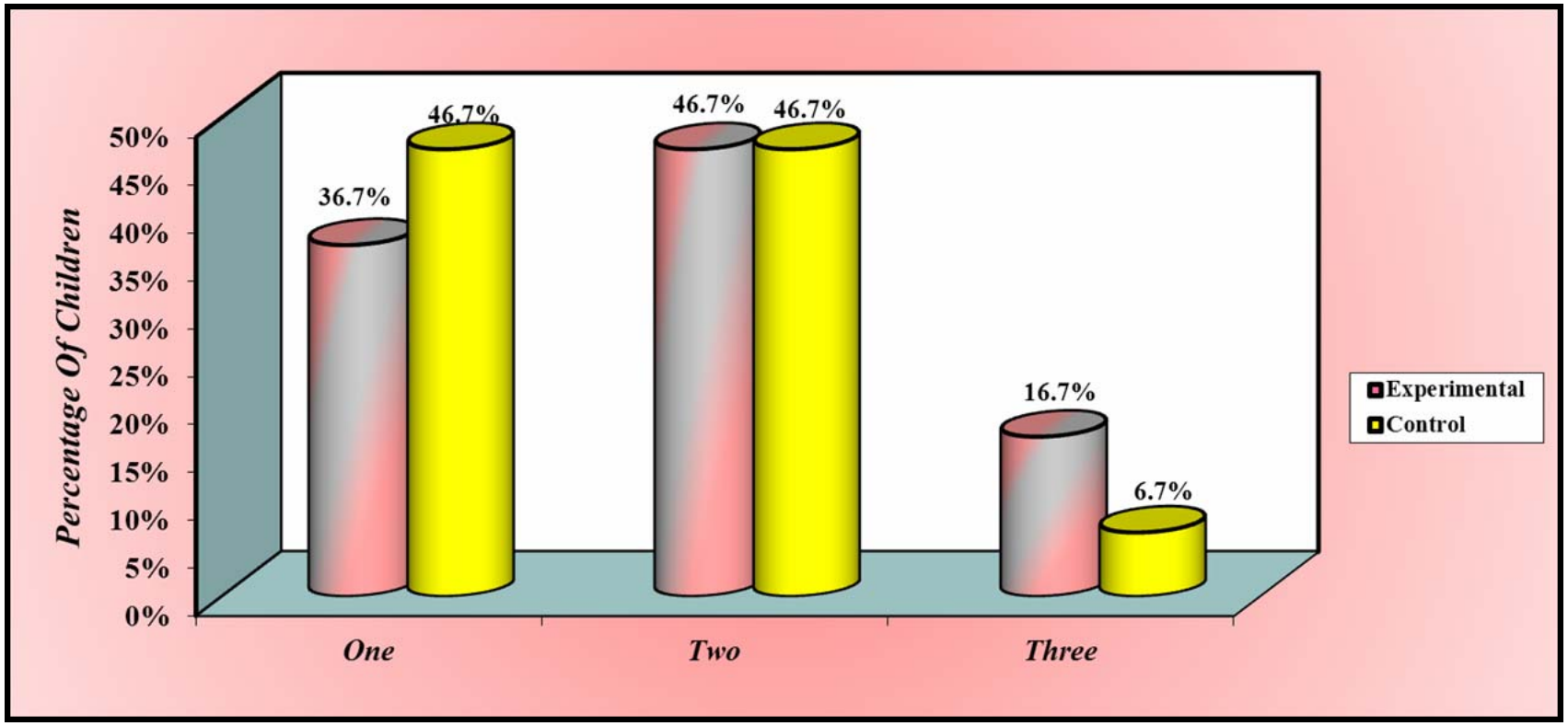


Figure 6 shows that majority of the children are born second (46.7%) in experimental group and (46.7%) in control group.

Figure 7: Demographic Variable - Language of Child

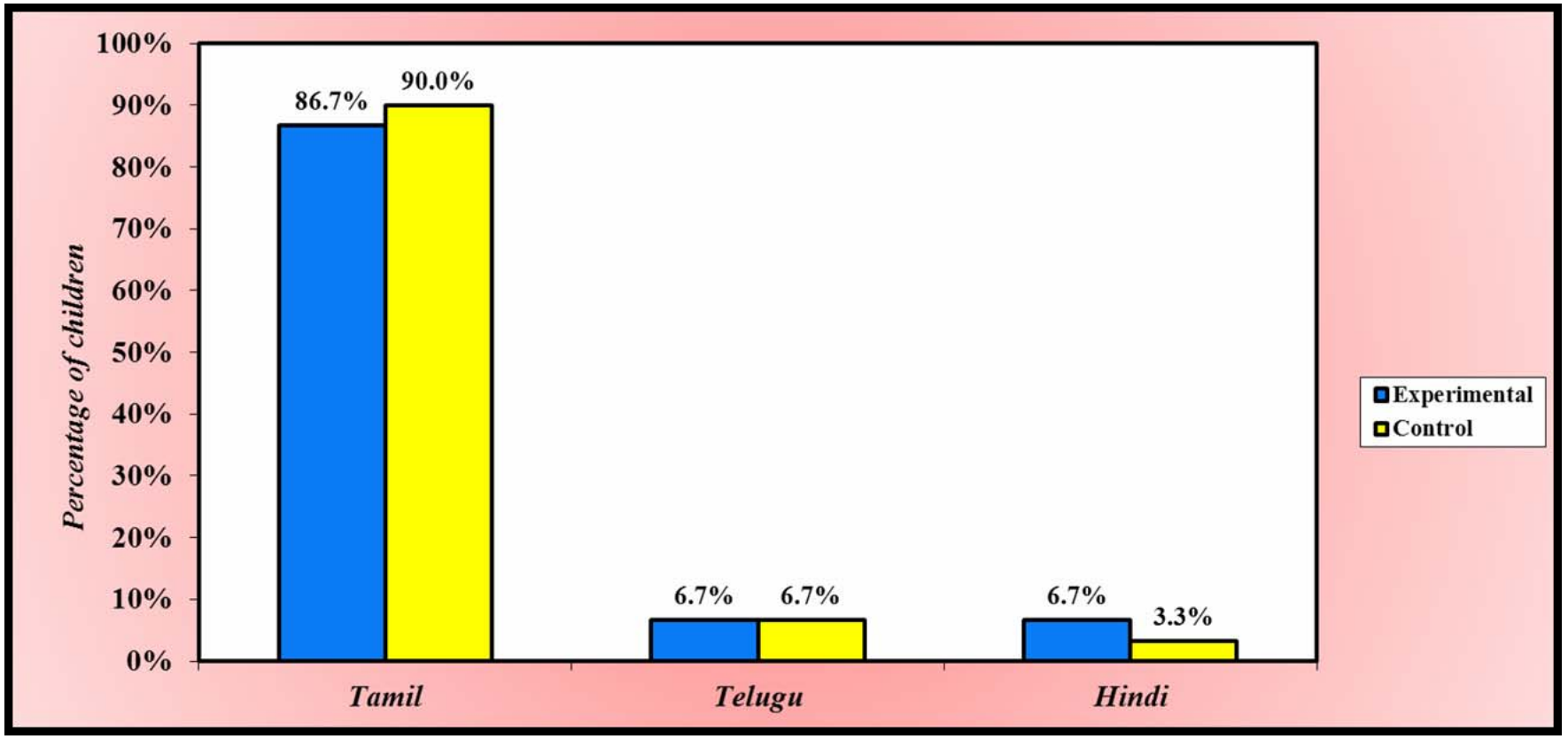


Figure 7 shows that majority of the children belong to Tamil language (86.7%) in experimental group and (90%) in control group.

Figure 8: Demographic Variable- Education of Child

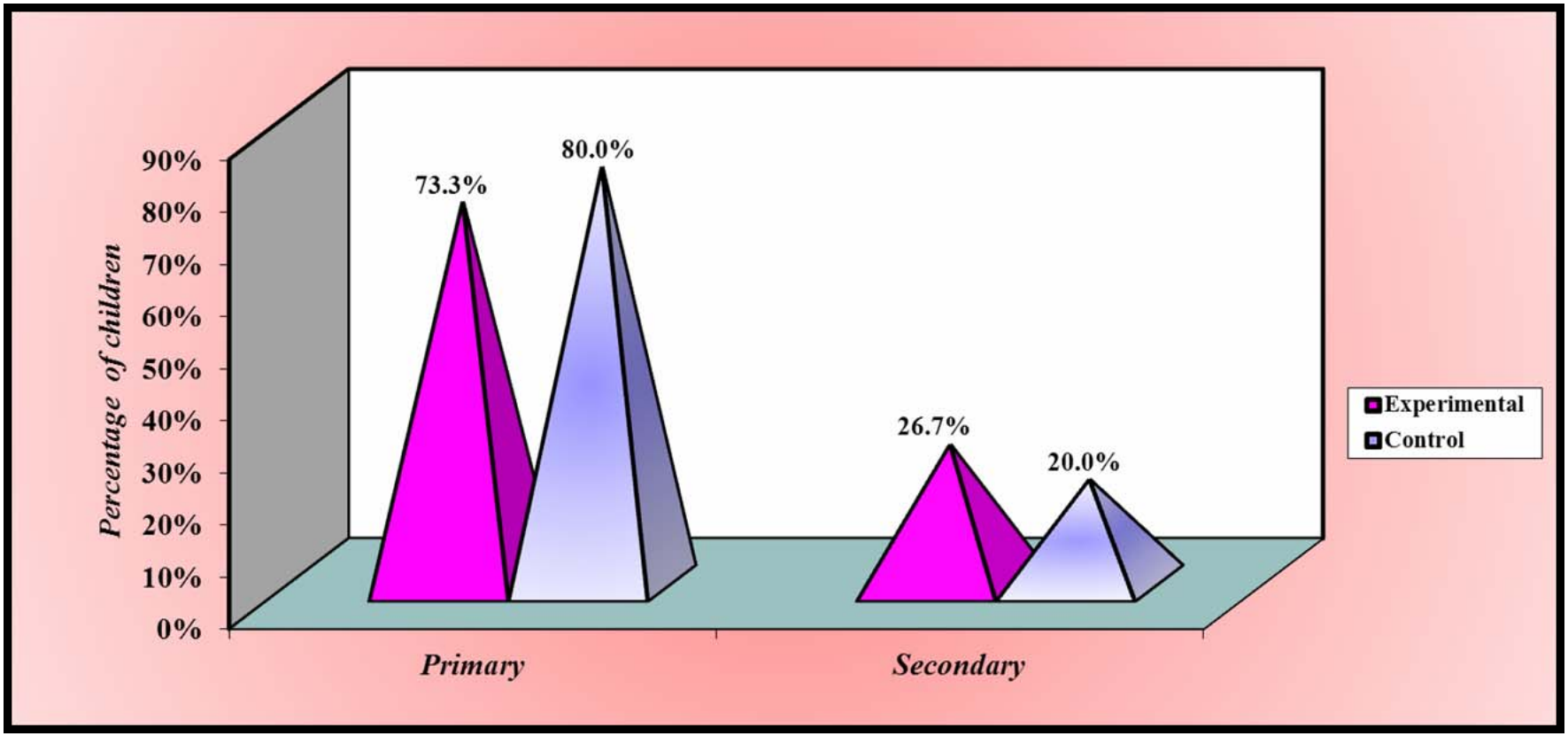


Figure 8 shows the education status of the children with majority in primary standards (73.3%) in experimental group and (80.0%) in control group.

Figure 9: Demographic Variable- Father's Education

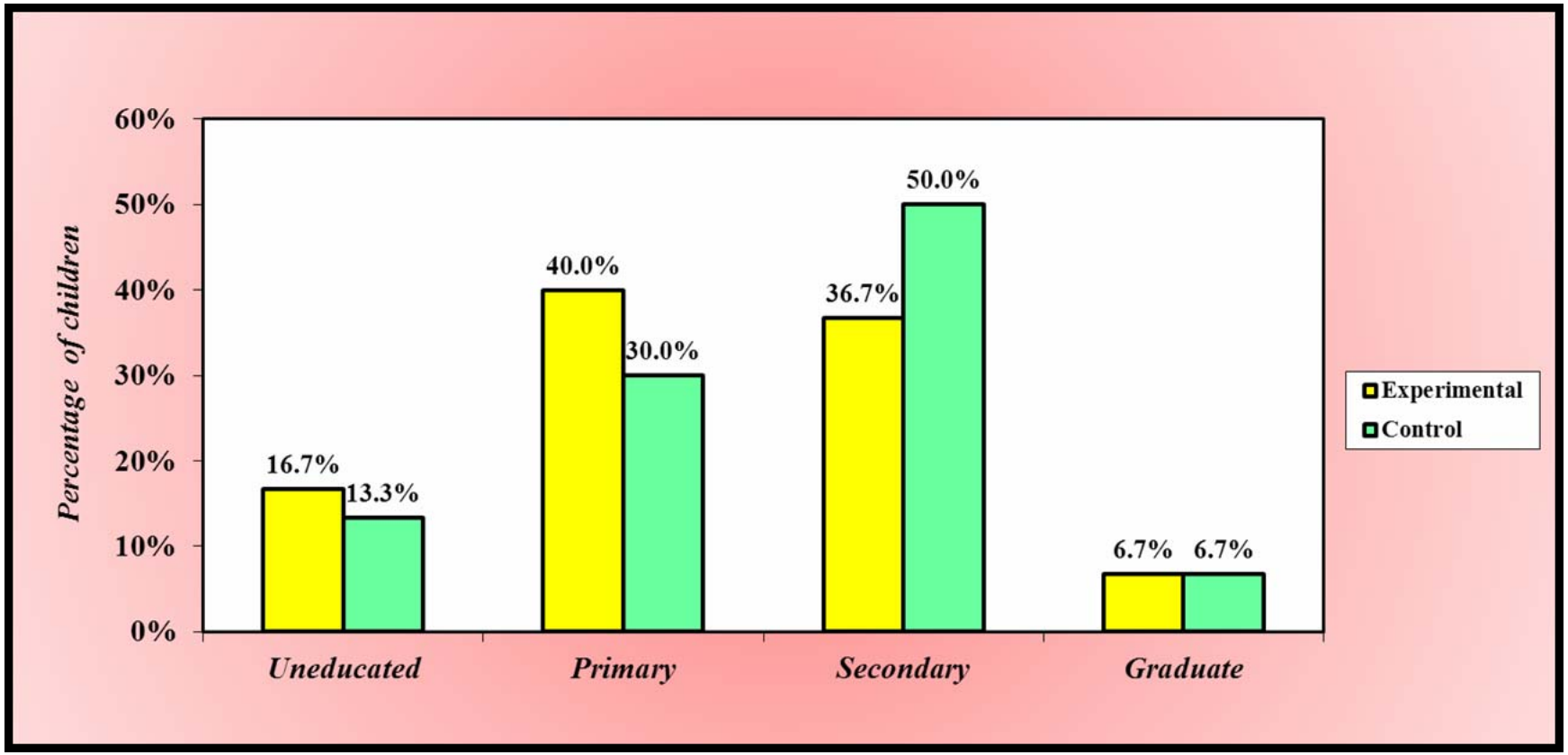


Figure 9 shows that majority of father's (53.3%) in experimental group and (60.0%) in control group belong to secondary education.

Figure 10: Demographic Variable- Mother's Education

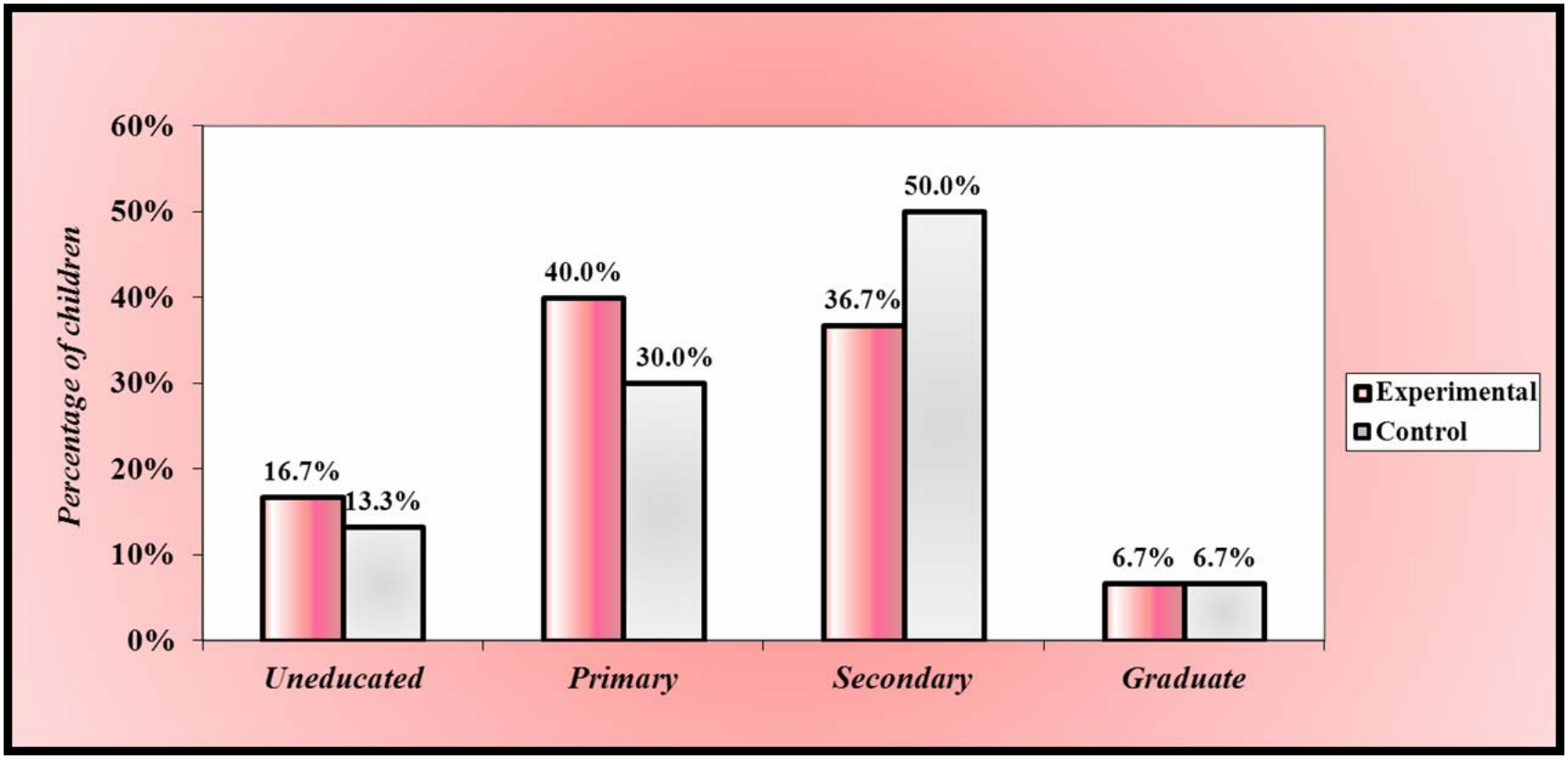


Figure 10 shows that majority of mother's (40.0%) in experimental group belong to primary education and (50.0%) in control group belong to secondary education.

Figure 11: Demographic Variable- Father's Occupation

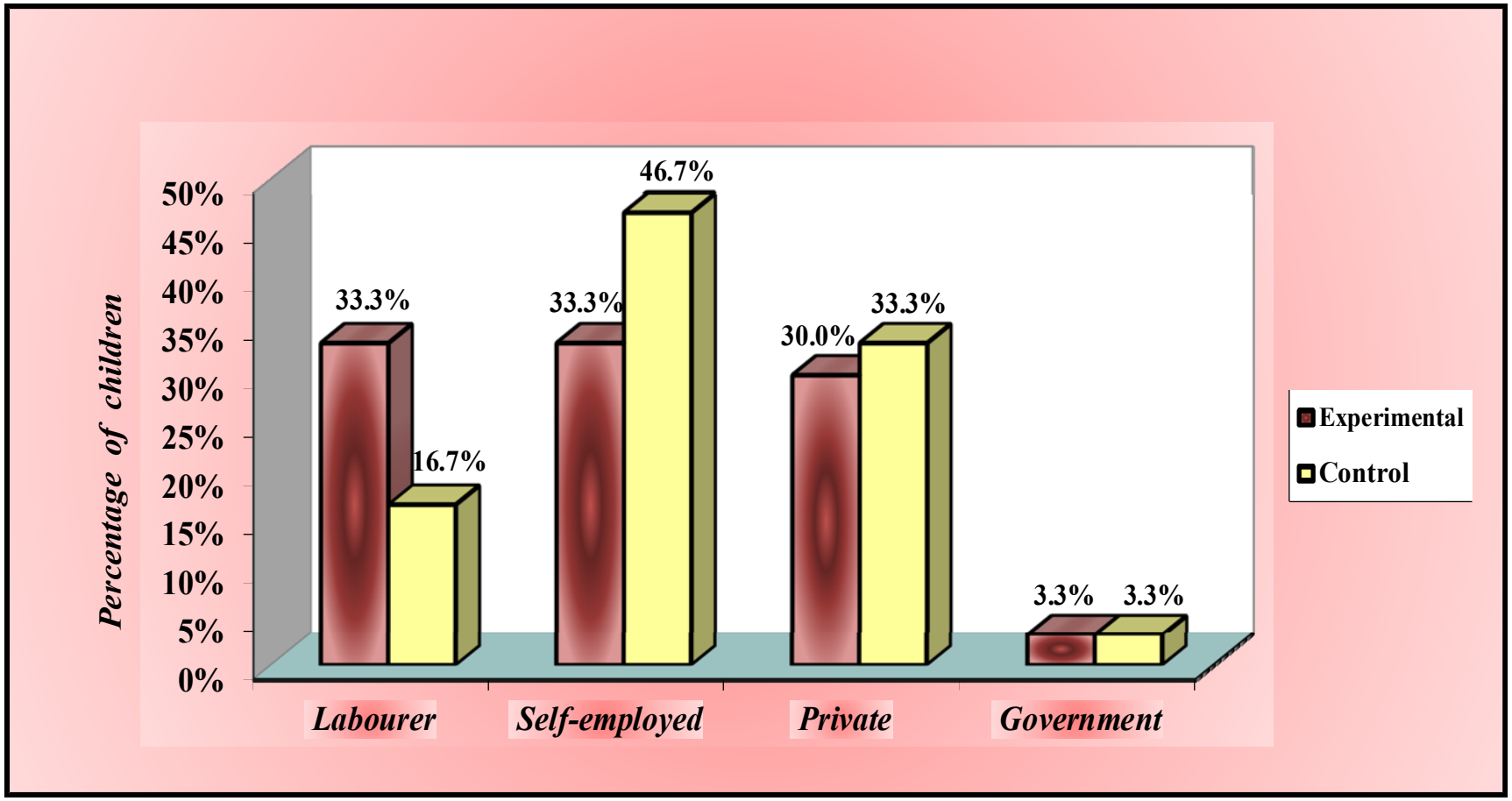


Figure 11 shows that majority of father's (33.3%) are labourers and (33.3%) are self-employed in experimental group and (46.7%) are self-employed in control group.

Figure 12: Demographic Variable- Mother's Occupation

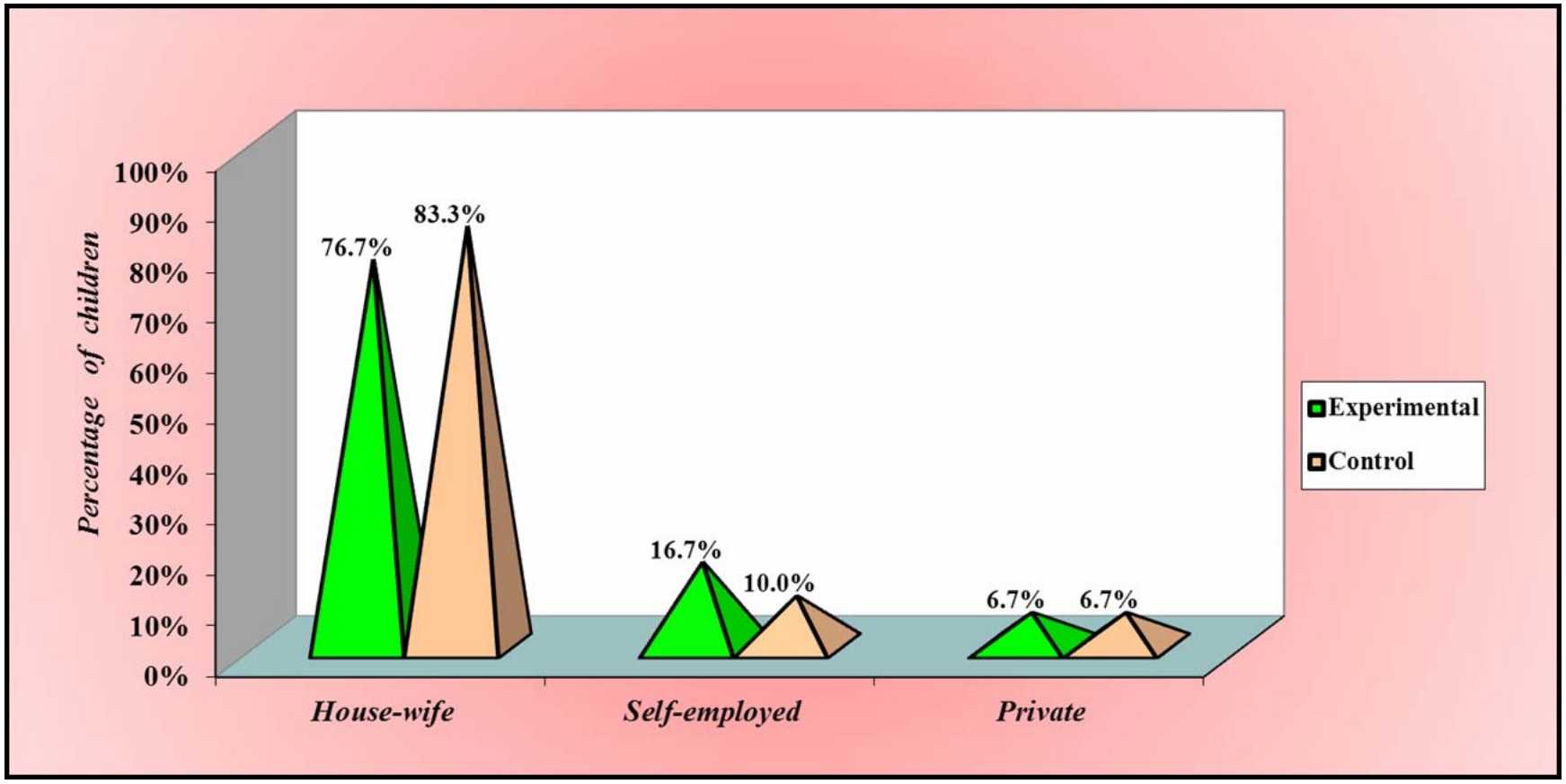


Figure 12 shows that majority of mother's (76.7%) in experimental group and (83.3%) in control group are house-wives.

Figure 13: Demographic Variable - Type Of Family

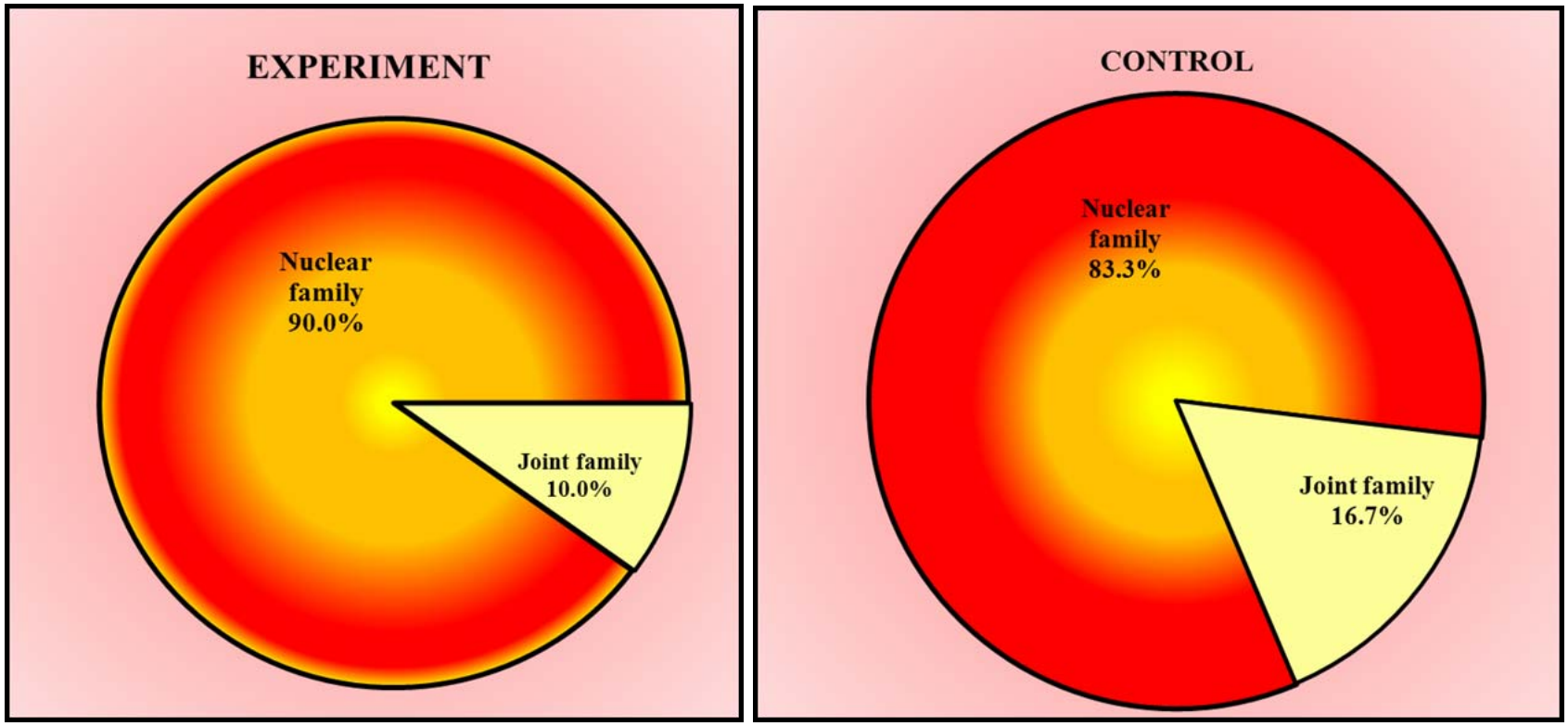


Figure 13 shows that majority of children are from nuclear family (90%) and (10%) from Joint family in experimental group and (83.3%) nuclear family and (16.7%) from Joint family in control group.

Figure 14: Demographic Variable -Place of Residence

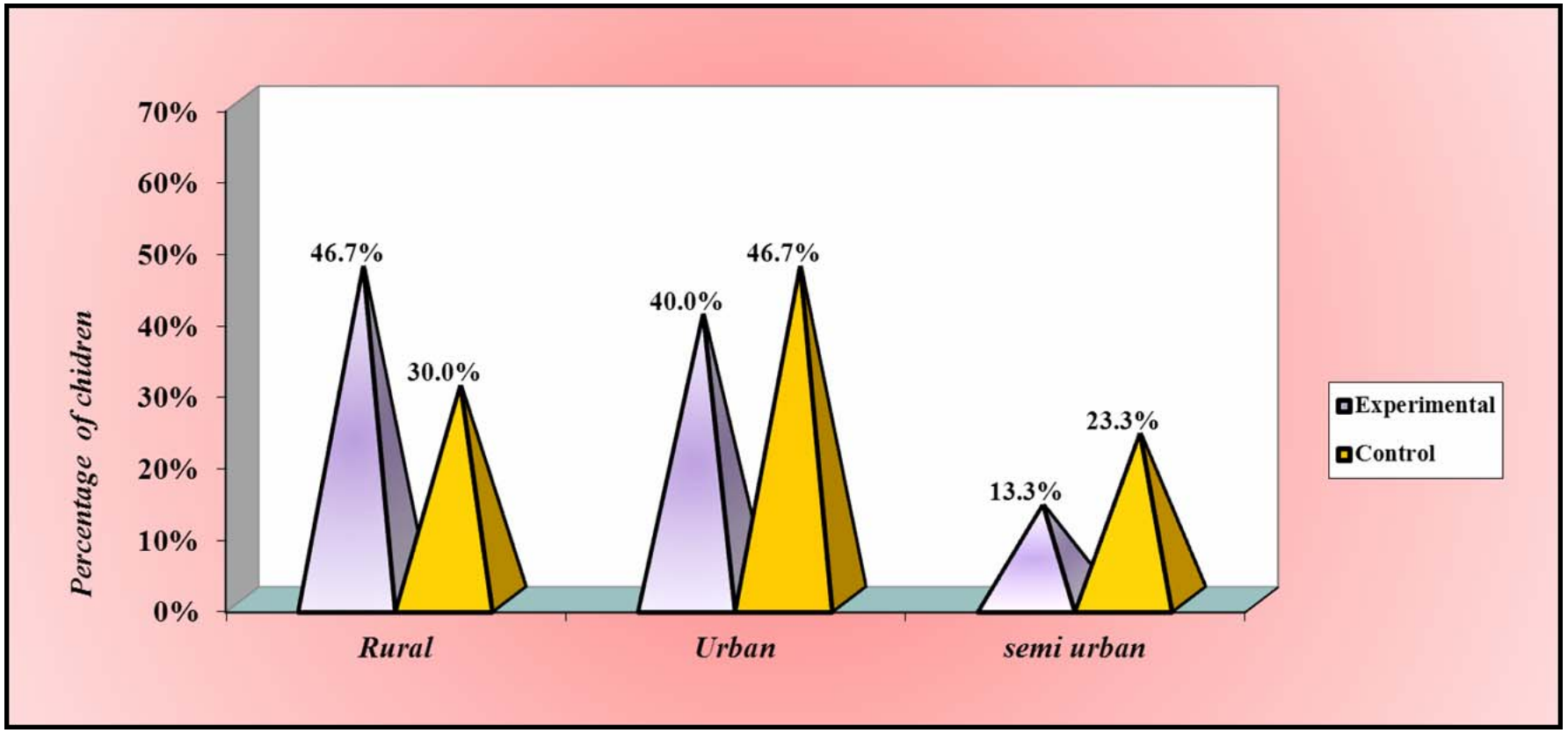


Figure 14 shows the place of residence of children with a majority (46.7%) from rural area in experimental group and (46.7 %) from urban area in control group.

Figure 15: Demographic Variable –Family Income

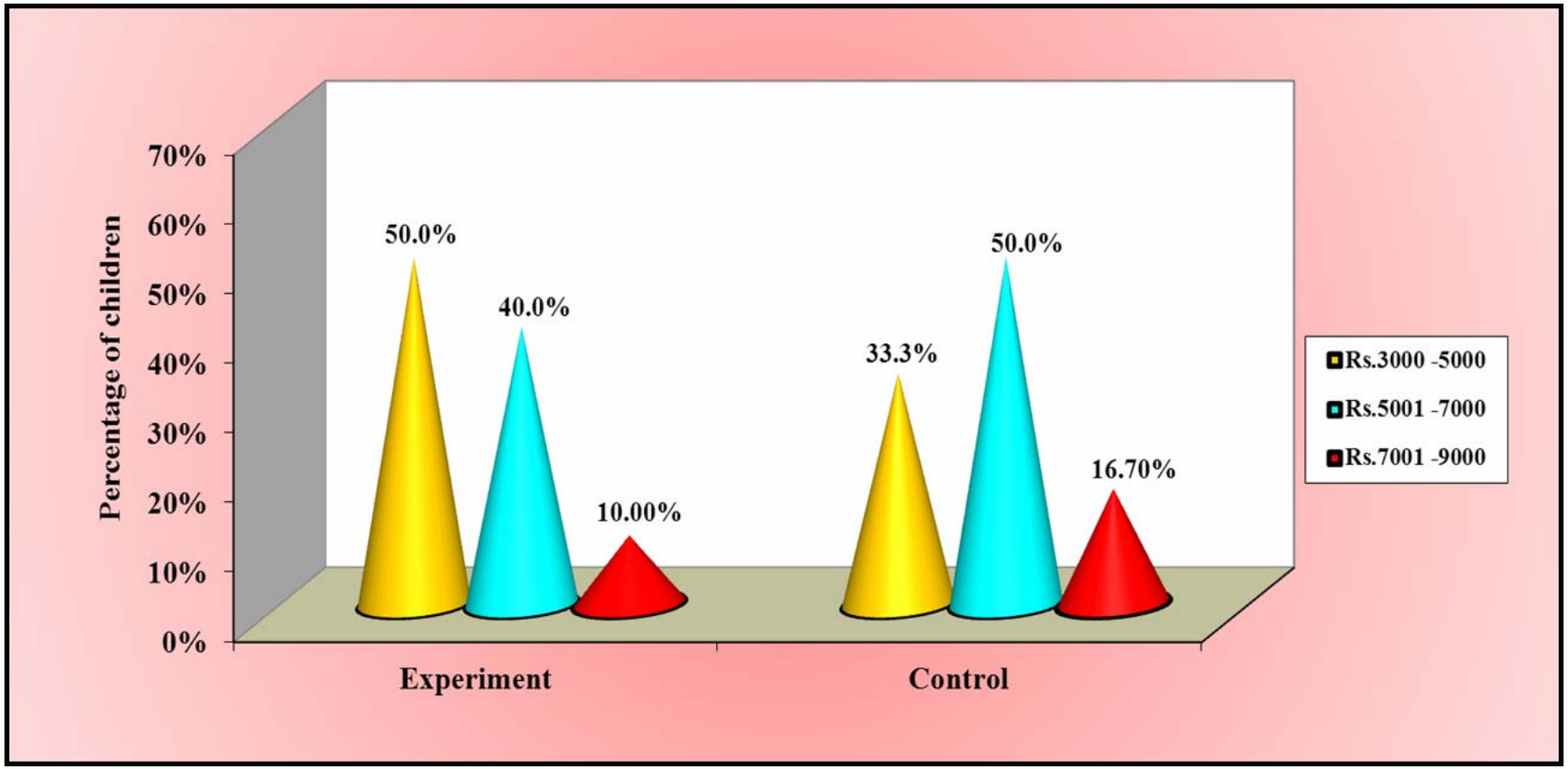


Figure 15 shows that the income status of the family is (50%) with Rs.3000-Rs 5000 in experiment group and (50%) with Rs. 5001-Rs.7000 in control group.

Figure 16: Demographic Variable –Family History of Cancer

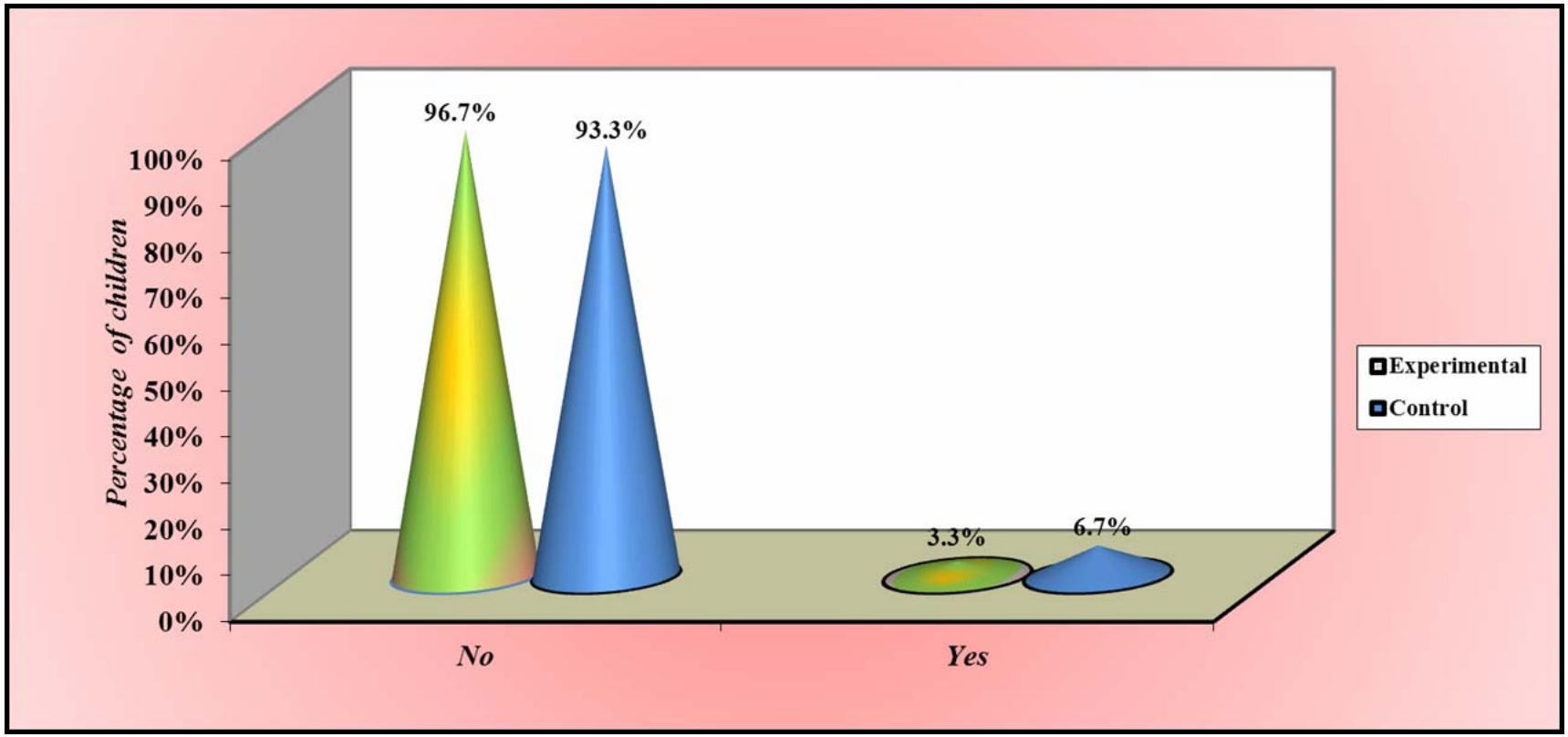


Figure 16 shows that there was no family history of cancer in both experimental group (96.7%) and (93.3%) in control group

Figure 17: Demographic Variable – Chemotherapy Cycle

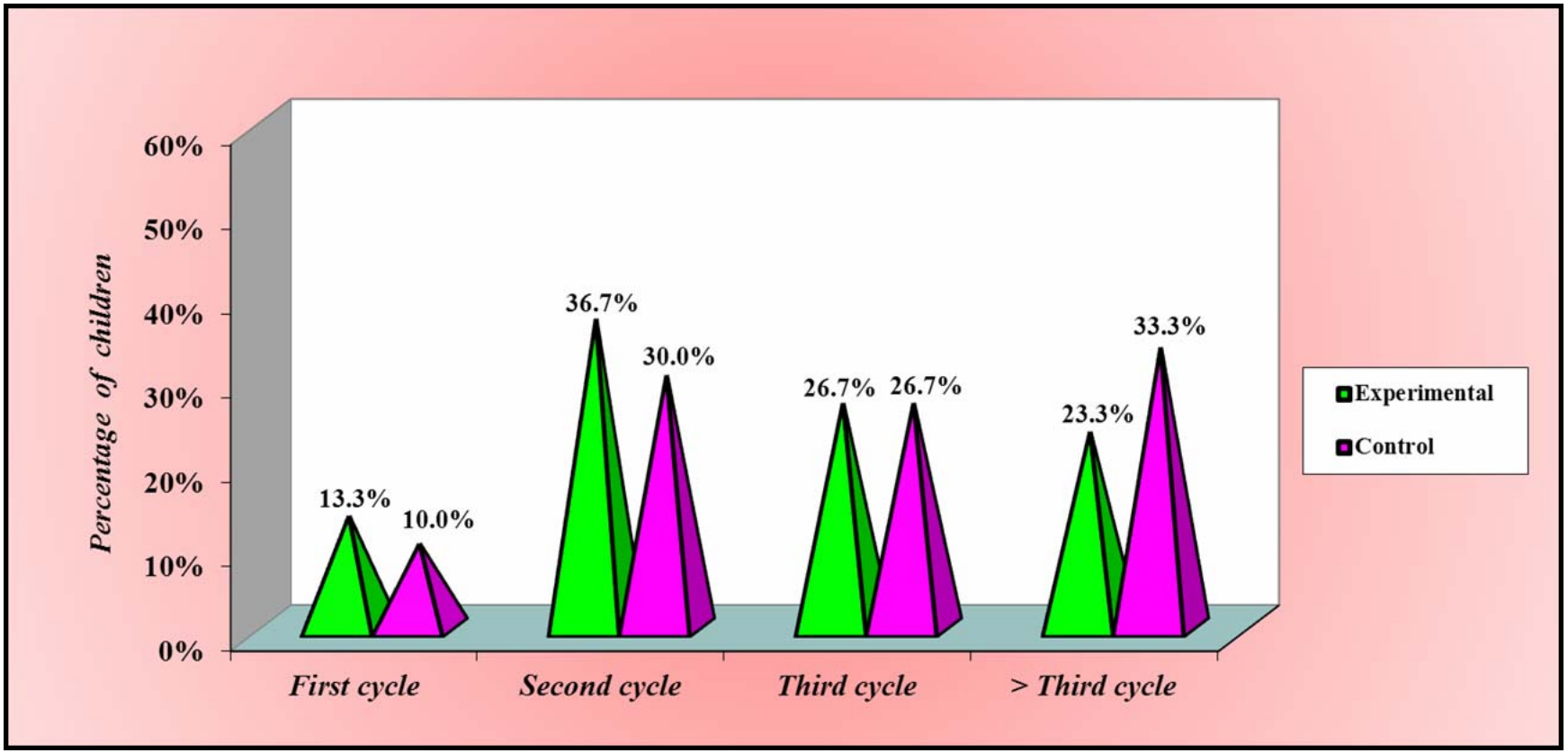


Figure 17 shows that majority of children, (36.7%) in experimental group and (30.0%) in control group were receiving second cycle of chemotherapy

SECTION B

Table -4.2.1: Post –Test Level of Pain in Control Group

(N=30)

Level of pain	Control group	
	Number of children	Percentage
No hurt	0	0.0%
Hurts little bit	0	0.0%
Hurts little more	0	0.0%
Hurts even more	16	53.3%
Hurts whole lot	11	36.7%
Hurts worst	3	10.0%
Total	30	100.0%

The above table describes the intensity of pain experienced by the children with routine care during intravenous cannulation in the control group.

Majority of children 16(53.3%) experienced pain with level as **"hurts even more",** 11(36.7%) with level as "**hurts whole lot**" and 3(10.0%) "**hurts worst**"

SECTION C

Table -4.3.1: Post-Test Level of Pain in Experimental Group

(N=30)

Level of pain	Experimental group	
	Number of children	Percentage
No hurt	0	0.0%
Hurts little bit	22	73.3%
Hurts little more	8	26.7%
Hurts even more	0	0.0%
Hurts whole lot	0	0.0%
Hurts worst	0	0.0%
Total	30	100.0%

The above table describes the intensity of pain experienced by the children with ice pack application in the experimental group.

The children experienced only minimum pain during intravenous cannulation 22(73.3%) experienced pain with level as **"hurts little bit"** and 8(26.7%) as **"hurts little more".** Overall there was reduction of level pain during intravenous cannulation with ice pack application.

Figure 18: Post-Test Level of Pain

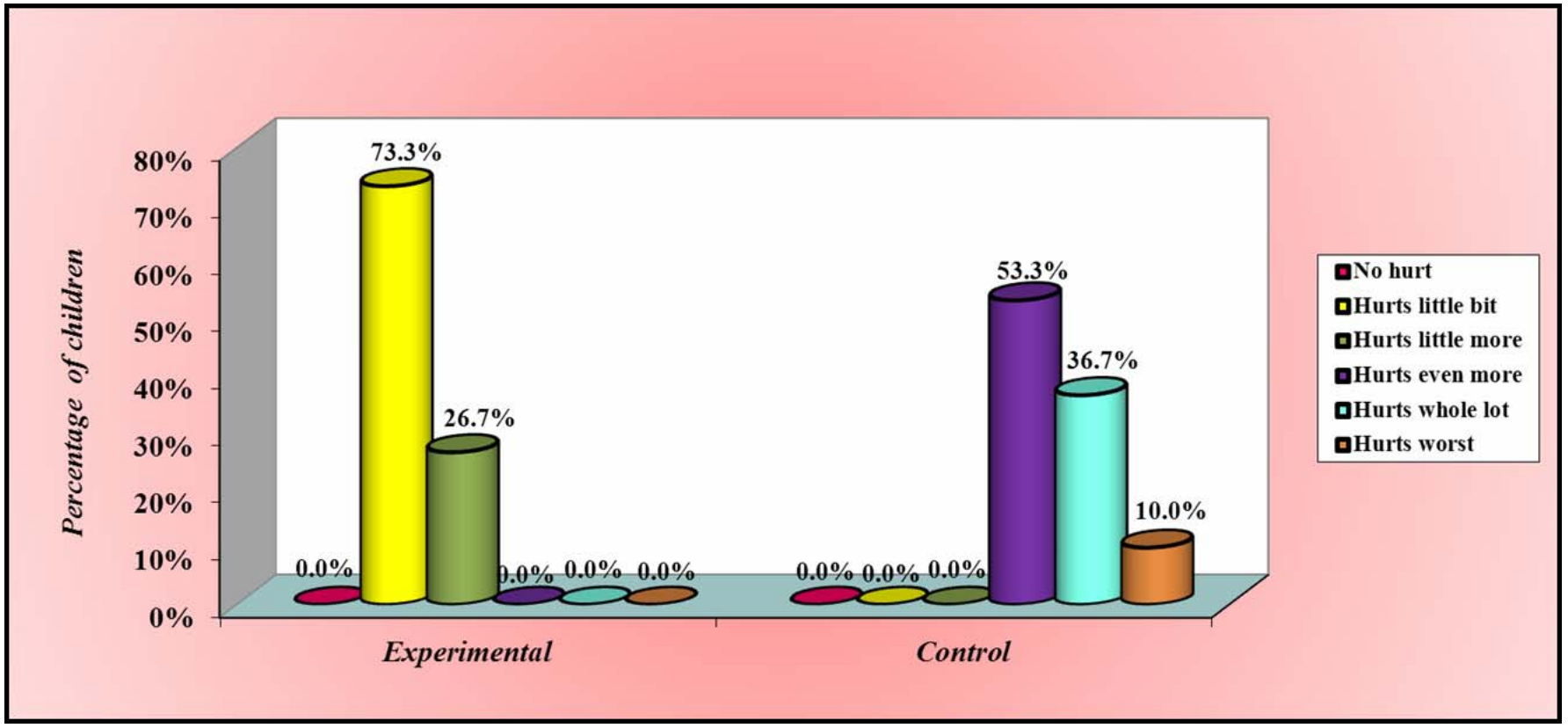


Figure 18 describes the level of pain experienced by the children is 73.3% in experimental group belonging to category "Hurts little bit" and 53.3% in control group belonging to category hurts even more.

SECTION D

Table -4.4.1: Comparison of the level of pain between experimental group and control group.

(N=60)

Level of pain	Experimental		Control		Chi square test
	Number	Percentage	Number	Percentage	
No hurt	0	0.0%	0	0.0%	***χ2=60.08*** ***P=0.001***** ***DF=4*** ***Significant***
Hurts little bit	22	73.3%	0	0.0%	
Hurts little more	8	26.7%	0	0.0%	
Hurts even more	0	0.0%	16	53.3%	
Hurts whole lot	0	0.0%	11	36.7%	
Hurts worst	0	0.0%	3	10.0%	

*** significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001**

The above table describes the comparison between the level of pain experienced by the experimental and control group

In experimental group, 22(73.3%) of the children were having **"hurts little bit"** level of pain and 8(26.7%) were having **"hurts little more"** level of pain.

In the control group, 16(53.3%) of the children were having **"hurts even more"** level of pain, 11(36.7%) were having and **"hurts whole lot"** level of pain and 3(10.0%) were having **"hurts worst"** level of pain.

The difference is large and it was statistically significant. Statistical significance was calculated using **"chi square test".**

Overall the children in the control group experienced more level of pain during intravenous cannulation with routine care when compared to the children in the experimental group who experienced minimum level of pain with ice pack application prior to intravenous cannulation.

TABLE -4.4.2

Comparison of pain scores between experimental and control group.

(N=60)

Group	Number of children	POST-TEST		Student's independent t-test
		Mean	SD	
Experimental	30	2.53	0.90	t=15.46 P=0.001***
Control	30	7.13	1.36	

*** significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001**

The above table describes the pain score between experimental and the control group

The experimental group were having 2.53 pain score with 0.90 SD and the control group were having7.13 pain score with 1.36 SD. The difference in the pain score is 4.60. This difference is large and was statistically very highly significant. Statistical significance was calculated by using **"student indenpendant t-test".**

TABLE -4.4.3

Effectiveness of Ice Pack Application between Experimental Group and Control Group

(N=60)

Group	Maximum score	Mean score	Mean difference with 95% CI	Percentage difference with 95%CI
Experimental	10	2.53	4.60 (4.00-5.19)	46.0% (40.0%-51.9%)
Control	10	7.13		

The above table describes the effectiveness of ice application on pain reduction between experimental and control group during intravenous cannulation in children receiving intravenous chemotherapy.

On an average, the children in experimental group were having 2.53 pain score and in the control group were having 7.13 pain score. The difference in the pain score between experimental and the control group was 4.60.This difference shows that ice application was effective in the experimental group.

Figure 19: Comparison of Mean Pain Score

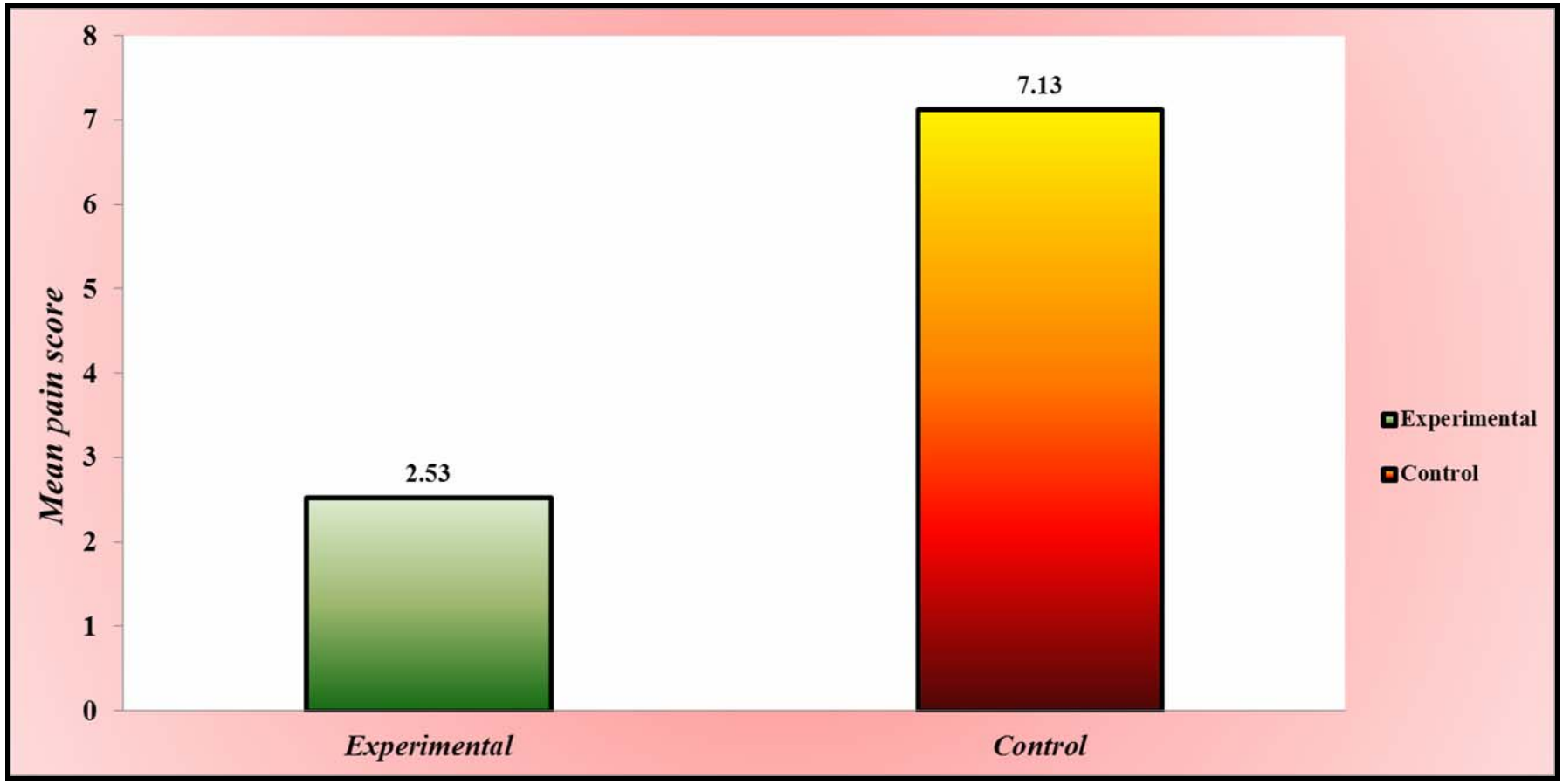


Figure 19 shows that the mean pain score was high in the control group (7.13) and least (2.53) in the experimental group.

SECTION E

Table -4.5.1: Association between Level of Post-Test Pain Score and Children Demographic Variables in Experimental Group

(N=30)

Demographic Variables		Pain Scale Score				Total	Chi square test
		Hurts little bit		Hurts little more			
		No	%	No	%		
Age	5 -6 years	1	20.0%	4	80.0%	5	$\chi 2=13.57$ p=0.01**
	6 -8 years	3	50.0%	3	50.0%	6	
	8 -10 years	10	90.9%	1	9.1%	11	
	10 -12 years	8	100.0%	0	0.0%	8	
Gender	Male	16	76.2%	5	23.8%	21	$\chi 2=0.29$ p=0.58
	Female	6	66.7%	3	33.3%	9	
Religion	Hindu	19	73.1%	7	26.9%	26	$\chi 2=3.84$ p=0.14
	Muslim	3	100.0%	0	0.0%	3	
	Christian	0	0.0%	1	100.0%	1	
Birth order	One	6	54.5%	5	45.5%	11	$\chi 2=4.00$ p=0.13
	Two	11	78.6%	3	21.4%	14	
	Three	5	100.0%	0	0.0%	5	
Language	Tamil	19	73.1%	7	26.9%	26	$\chi 2=1.28$ p=0.52
	Telugu	1	50.0%	1	50.0%	2	
	Hindi	2	100.0%	0	0.0%	2	
Child's education	Primary	14	58.3%	10	41.7%	24	$\chi 2=4.85$ p=0.03*
	Secondary	8	100.0%	0	16.7%	6	

*** Significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001**

The above table describes the association between the levels of pain reduction with the demographic variables of the children.

Regarding age, 8children (100%) between age groups 10-12 years were benefited more having **"hurts little bit"** level of pain with **$\chi 2=13.57$** and **p=0.01**** describing high significance in the reduction of pain.

Regarding child's education, children 8(100%) of secondary school education were benefited having "**hurts little bit"** level of pain with**$\chi 2=4.85$** and **p=0.03*** describing significance in the reduction of pain.

Overall the children 10-12 years of age and children with secondary education are benefited more. The statistical significance was calculated using **"chi square test"**

There were no significant association analysed in relation to the gender ($\chi 2=0.29$ p=0.58), religion ($\chi 2=3.84$ p=0.14), birth order ($\chi 2=4.00$, p=0.13) and language of the child ($\chi 2= 1.28$, p= 0.52).

Table -4.5.2: Association between level of post-test pain score and parent's information variables in experimental group

(N=30)

Demographic Variables		Pain Scale Score				Total	Chi square test
		Hurts little bit		Hurts little more			
		No	%	No	%		
Father's education	Uneducated	1	33.3%	2	66.7%	3	$\chi 2=3.61$ p=0.30
	Primary	7	77.8%	2	22.2%	9	
	Secondary	13	81.3%	3	18.8%	16	
	Graduate	1	50.0%	1	50.0%	2	
Mother's education	Uneducated	1	20.0%	4	80.0%	5	$\chi 2=12.27$ p=0.01**
	Primary	8	66.7%	4	33.3%	12	
	Secondary	11	100.0%	0	0.0%	11	
	Graduate	2	100.0%	0	0.0%	2	
Father's occupation	Labourer	6	60.0%	4	40.0%	10	$\chi 2=1.59$ p=0.66
	Self - employed	8	80.0%	2	20.0%	10	
	Private	7	77.8%	2	22.2%	9	
	Government	1	100.0%	0	0.0%	1	
Mother's occupation	Housewife	18	78.3%	5	21.7%	23	$\chi 2=1.29$ p=0.52
	Self - employed	3	60.0%	2	40.0%	5	
	Private	1	50.0%	1	50.0%	2	
Family Income	Rs.3000 - 5000	11	73.3%	4	26.7%	15	$\chi 2=0.08$ p=0.95
	Rs.5001 - 7000	9	75.0%	3	25.0%	12	
	Rs.7001 - 9000	2	66.7%	1	33.3%	3	
Type of family	Nuclear family	20	74.1%	7	25.9%	27	$\chi 2=0.08$ p=0.78
	Joint family	2	66.7%	1	33.3%	3	

Demographic Variables		Pain Scale Score				Total	Chi square test
		Hurts little bit		Hurts little more			
		No	%	No	%		
Area of residence	Rural	12	85.7%	2	14.3%	14	$\chi 2=2.48$ p=0.28
	Urban	7	58.3%	5	41.7%	12	
	Semi urban	3	75.0%	1	25.0%	4	

*** Significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001**

The above table describes the association between the levels of pain reduction with the demographic variables of the parents.

With regards to the mother's education status the children of mothers with secondary education 11(100%) and graduates 2(100%) were benefited more having **"hurts little bit"** level of pain with **($\chi 2=12.27$ p=0.01**)** describing high significance in the reduction of pain.

Overall the more educated mother's children are benefited the more. The statistical significance was calculated by using "chi square test"

There was no association in regard to the father's education ($\chi 2=3.61$, p=0.30), father's occupation ($\chi 2=1.59$, p=0.66), mother's occupation ($\chi 2=1.29$, p=0.52), family income ($\chi 2=0.08$, p=0.95), type of family ($\chi 2=0.08$, p=0.78) and the area of residence of the family ($\chi 2=2.48$, p=0.28).

Table -4.5.3: Association between level of posttest pain score and disease related information in experimental group

(N=30)

Cancer Details		Pain Scale Score				Total	Chi square test
		Hurts little bit		Hurts little more			
		No	%	No	%		
Family H/O cancer	No	21	72.4%	8	27.6%	29	$\chi 2=0.37$ p=0.54
	Yes	1	100.0%	0	0.0%	1	
Chemotherapy cycle	First cycle	1	25.0%	3	75.0%	4	$\chi 2=8.67$ p=0.03*
	Second cycle	7	63.6%	4	36.4%	11	
	Third cycle	7	87.5%	1	12.5%	8	
	> Third cycle	7	100.0%	0	0.0%	7	

*** Significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001**

The above table describes the association between the levels of pain reduction with disease related variables

There was no association between the level of pain reduction and family history of cancer ($\chi 2=0.37$ p=0.54)

Regarding the chemotherapy cycles there was significant reduction of pain among children who had more than three cycles of chemotherapy with **($\chi 2=8.67$ p=0.03*).**

Figure 20: Association between post-test level of pain and children age (experimental group)

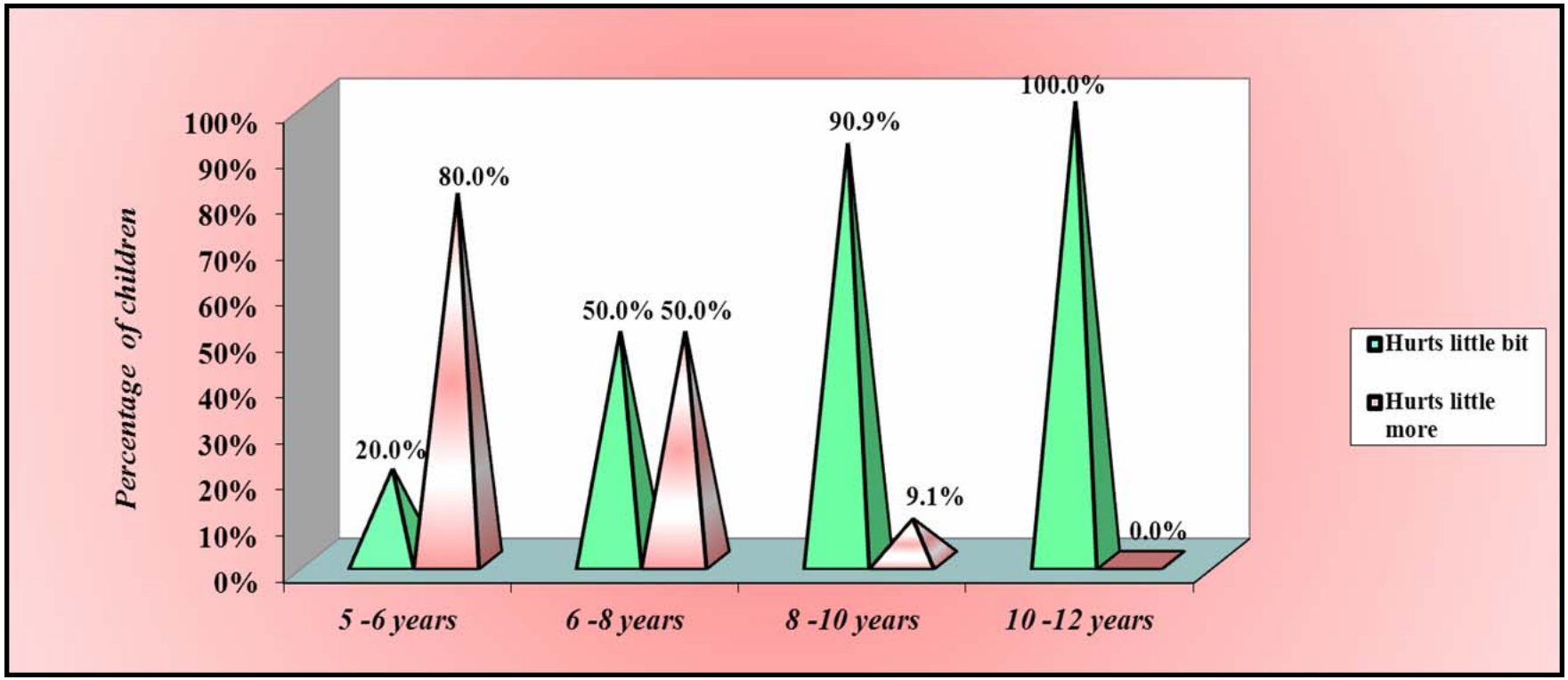


Figure 20 describes that the level of pain between age groups 10-12 years was (100%) belonging to the category "Hurts little bit" in experimental group and (80%)between age groups 5-6 years belonging to the category "Hurts little more" in control group.

Figure 21: Association between post-test level of pain and children education (experimental group)

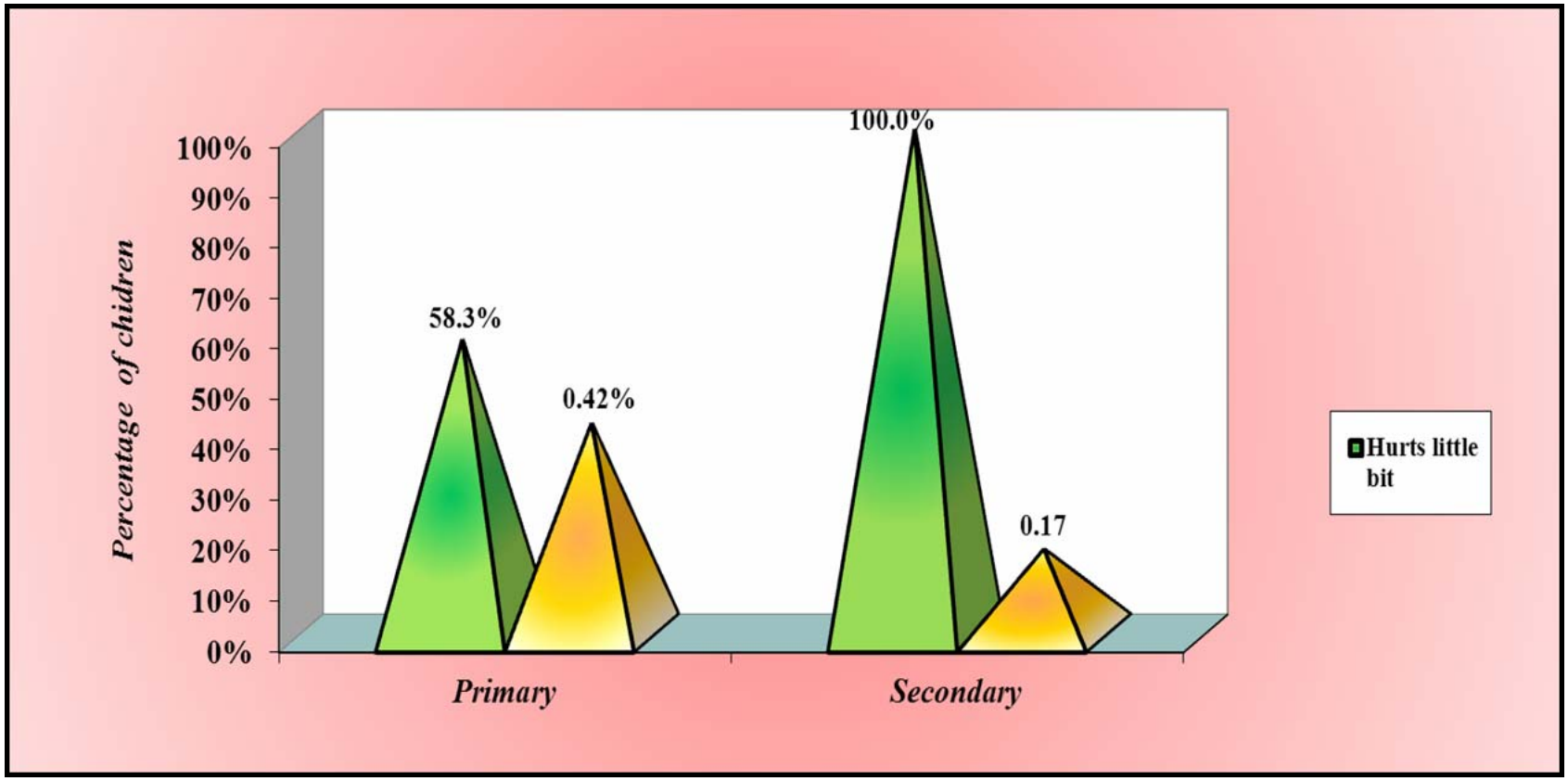


Figure 21 describes that the majority of children was of Secondary education status experiencing (100%) intensity of pain and (58.3%) intensity of pain in primary education belonging to category "Hurts little bit"

Figure 22: Association between post-test level of pain and mother education (experimental group)

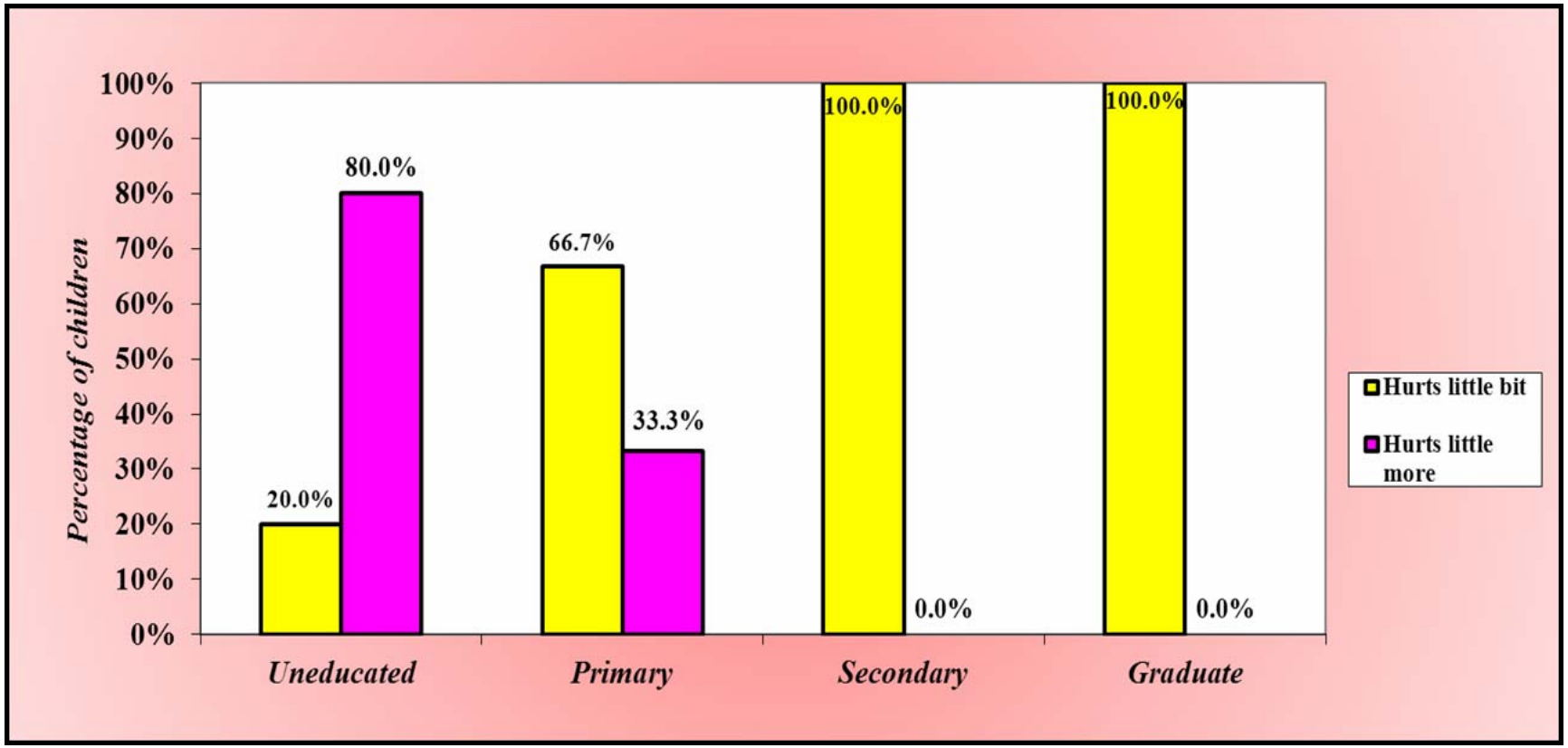


Figure 22 describes that the level of pain experienced by the children was (100%) belonging to category of "Hurts little bit" with mothers of secondary educational status and graduates.

Figure 23: Association between the post-test level of pain and number of chemo cycles

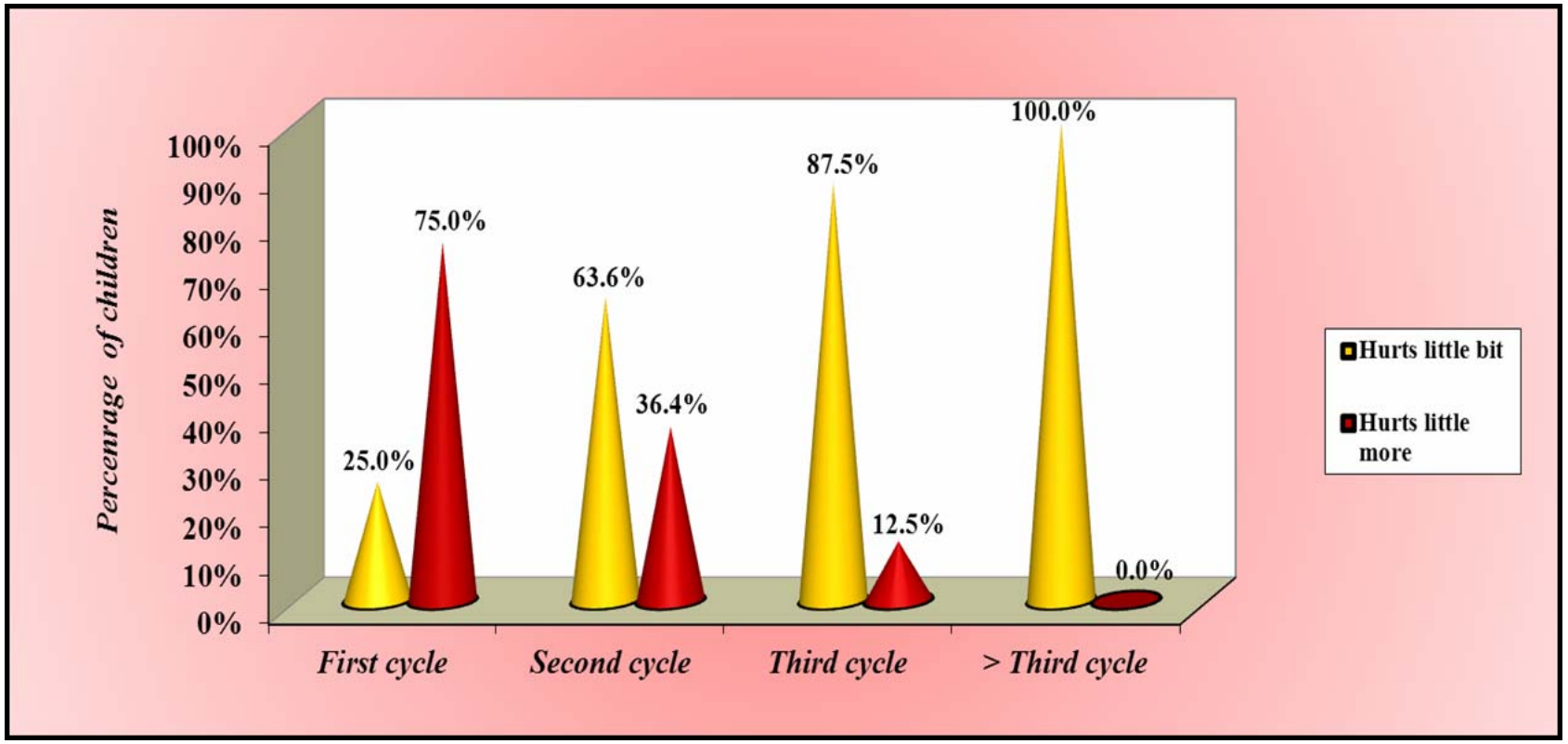


Figure 23 describes that the level of pain was (100%) belonging to the category "Hurts little bit" and (75.5%) belonging to the category "Hurts little more.

CHAPTER - V
DISCUSSION

This study was conducted to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy. The discussions of the study findings are presented in this chapter.

DESCRIPTION OF DEMOGRAPHIC VARIABLES

EXPERIMENTAL GROUP

Demographic information of Children

The demographic data analysis showed that around 11(36.7%) were between the age groups 8-10 years, 8(26.7%) between 10-12 years, 6(20.0%) between 5(16.7%) between 5-6 years, out of which 21(70%) were male and 9(30%) were female children.

In relation to religion 26(86.7%) were Hindus, 3(10.0%) were Muslims and 1(3.3%) were Christians with majority 14(46.7%) as second born children, 11(36.7%) as first and 5(16.7%) as third born children for their parents.

Considering the language majority of the children 26(86.7%) belonged to Tamil, 2(6.7%) Telugu and only 2(6.7%) belonged to Hindi language.

Regarding the educational status most of the children 22(73.3%) were studying primary school education and 8(26.7%) were studying secondary school education.

Demographic information of Parents

Considering the father's educational status about 16(53.3%) studied till secondary education, 9(30%) primary education, 3(10.0%) were uneducated and only 2(6.7%) were graduates with majority of them as 10 (33.3%) labourers and 10(33.3%) self-employed, 9(30%) were working in private companies and only 1(3.3%) was a government employee.

Regarding the mother's educational status about 12(40.0%) studied primary school education, 11(36.7%) secondary education, 5(16.7%) uneducated and only 2(6.7%) were graduates with majority of them 23(76.7%) as house-wives, 5(16.7%) self-employed and 2(6.7%) working in private companies

Regarding the income of the family 15(50%) was between Rs3000-Rs5000, 12(40%) between Rs5001-Rs7000 and 3(10.0%) between Rs7001-Rs9000.

Majority 27(90%) were nuclear families and 3(10.0%) were joint families among which 14(46.7%) reside in rural area, 12(40.0%) in urban area and 4(13.3%) in semi-urban area.

Information related to disease (cancer)

Regarding the family history of cancer in only 1(3.3%) there was an incidence of cancer in the family and with 29(96.7%) no incidence of cancer in the family

Among 30 children around 11(36.7%) had come for second chemo cycle, 8(26.7%) for third chemo cycle, 7(23.3%) had more than three cycles of chemotherapy and only 4(13.3%) had come for first cycle of chemotherapy.

CONTROL GROUP

Demographic information of Children:

Among 30 children 11 (36.7%) were between the age groups 6-8 years, 8(26.7%) between 10-12 years, 6(20.0%) between 8-10 years and 5(16.7%) between 5-6 years, with 19(63.3%) male and 11(36.7%) female children.

Regarding the religion of children 27 (90.0%) were Hindus, 2(6.7%) were Muslims and 1(3.3%) were Christians with 14(46.7%) born as first, 14(46.7%) as second and 2(6.7%) as third children. In the control group 27(90%) belonged to Tamil, 2(6.7%) to Telugu and 1(3.3%) to Hindi language.

Regarding the education status of the children 24(80%) were doing their primary school education and 6(20%) were doing their secondary school education

Demographic information of Parents

Regarding father's education status 18(60.0%) completed secondary education, 7(23.3%) primary education, 3(10.0%) had no education and only 2(6.7%) were graduates and majority of the fathers14 (46.7%) were self-employed, 10(33.3%) working in private companies, 5(16.7%) as labourers and only 1(3.3%) were government employee.

With regards to mothers education status about 15(50%) completed their secondary school education, 9(30.0%) Primary education, 4(13.3%) uneducated and only 2(6.7%) were graduates and most of them 25(83.3%) were housewives, 3(10.0%) self-employed, 2 (6.7%) working in private companies and there were no government employees.

The monthly income of the family in about 15(50%) was between Rs5001- Rs7000, 10(33.3%) between Rs3000-Rs5000 and only 5(16.7%) was between Rs7001-Rs9000.

With respect to the type of family 25(83.3%) were nuclear family and the remaining 5(16.7%) belonged to joint family with about 14(46.7%) residing in urban area, 9(30.0%) in rural area and 7(23.3%) residing in semi-urban area.

Information related to cancer

Regarding family history of cancer about 28(93.3%) there was no incidence and only 2(6.7%) there was an incidence of cancer in their families.

Among 30 children about 10(33.3%) were receiving more than three cycles of chemotherapy, 9(30.0%) had come for second chemo cycle, 8(26.7%) were for third chemo cycle and only 3(10.0%) had come for the first cycle of chemotherapy.

The first objective of the study was to assess the intensity of pain prior to intravenous cannulation with routine care in children 5-12 years of age receiving intravenous chemotherapy in control group.

The study findings revealed that among 30 children who received intravenous chemotherapy about 16(53.3%) experienced pain with level as “hurts even more”, 11(36.7%) with level as “hurts whole lot” and 3(10.0%) “hurts worst”. The intensity of pain was assessed by using Wong Baker’s Faces pain Scale. Therefore it was determined that the children experienced more pain during intravenous cannulation in the control group. This objective was supported by the following study.

Lander J, Fowler-Kerry S, Oberle S., (1992) conducted a study on pain experienced by children during venipuncture. In the study 514 children of 5-17 years of age who had venipuncture performed were analysed by using the visual analogue pain scale revealed that age and

anxiety were the significant predictors of pain. The results of the study concluded that venipuncture pain can be recommended for the study of issues in children's pain.

The second objective of the study was to assess the effectiveness of ice pack application prior to intravenous cannulation on pain reduction in children 5 -12 years of age receiving intravenous chemotherapy in experimental group.

The study findings revealed that among 30 children who had come to receive intravenous chemotherapy about 22(73.3%) were having "*hurts little bit"* level of pain and 8(26.7%) were having *"hurts little more"* level of pain. The intensity of pain was assessed by using Wong Baker's Faces pain Scale. Overall there was reduction of level pain during intravenous cannulation with ice pack application in the experimental group. Hence the hypothesis formulated was accepted

Huseyin Aygun, Erol Armağan,et al(2012) conducted a study on 120 children categorised into three groups with 2 experiment groups undergoing intravenous cannulation with one minute application of ice prior to cannulation and the other group with lidocaine-procaine cream. The third control group underwent cannulation without any intervention. The study concluded that ice application is effective than lidocaine-procaine cream

The third objective of the study was to compare the level of pain between experimental and control group.

This objective determined the co-relation between experimental and control group on the level of pain experienced by the children during intravenous cannulation .The student **"chi square"** test revealed (***P=0.001***)*** that there was a large difference in the level of pain experienced by the children between experimental and control group.

In the control group, 16(53.3%) of the children were having **"hurts even more"** level of pain, 11(36.7%) were having and **"hurts whole lot"** level of pain and 3(10.0%) were having **"hurts worst"** level of pain with routine care during intravenous cannulation in children 5-12 years of age receiving intravenous chemotherapy.

With ice pack application there was reduction in pain level in experimental group, 22(73.3%) of the children were having **"hurts little bit"** level of pain and 8(26.7%) were having **"hurts little more"** level of pain while intravenous cannulation in children 5-12 years of age receiving intravenous chemotherapy.

The comparison of pain scores between experimental and control group calculated by using **"student indenpendant t-test".** The test showed that there was 2.53 pain score with 0.90 SD in the experimental group and 7.13 pain score with 1.36 SD in the control group. The difference in the pain score was 4.60. This difference was large and was statistically highly significant with **P=0.001***.**

Navjot Kiran, Sukhjit Kaur., (2013) conducted a quasi-experimental study in 100 samples (50 in experiment group and 50 in control group), to assess the effectiveness of ice pack application at the site prior to venepuncture for 3 minutes in children of 3-7years of age who were receiving chemotherapy. Pain was assessed in both the groups with FLACC behaviour pain assessment scale. The mean pain score between the two groups were found to be significant. The study concluded that ice pack application significantly decreased the intensity of pain and was found to be the safe, cheap, easy and effective method to reduce procedural pain among children.

T he fourth objective of thestudy was to compare the effectiveness of ice pack application on pain reduction prior to intravenous cannulation between experimental and control group.

The fourth objective was to determine by the mean pain score between the experiment and control group .The children in experimental group were having 2.53 pain score and in the control group were having 7.13 pain score. The difference in the pain score between experimental group and control group was 4.60.This difference showed that ice application was effective in the experimental group.

Inal S, Kelleci M,(2012) conducted a study with randomized controlled trial on 120 children undergoing phlebotomy. The subjects were randomly assigned to control group (no intervention) or an experimental group that received external cold and vibration via a device called Buzzy. External cold and vibration were applied just before the blood specimen collection procedure and continued until the end of the procedure. Procedural pain was assessed via the faces pain scale-revised along with self-report of children, and parents' and observer's reports. The experimental group showed significantly lower pain and anxiety levels compared to the control group during the blood specimen collection procedure.

The fifth objective of the study was to associate the effectiveness of ice application on pain reduction with the selected demographic variables in experimental group.

Children information

The "chi square test" showed that the association with post-test level of pain in regard to the age and the education status of the children were statistically significant ($p < 0.05$)

Regarding age,8children (100%) between age groups 10-12 years were benefited more having **"hurts little bit"** level of pain with **$\chi 2=13.57$** and **p=0.01**** describing high significance in the reduction of pain.

Regarding child's education, children 8(100%) of secondary school education were benefited having "**hurts little bit"** level of pain with**χ2=4.85** and **p=0.03*** describing significance in the reduction of pain.

There were no significant association analysed in relation to the gender (χ2=0.29 p=0.58), religion (χ2=3.84 p=0.14), birth order (χ2=4.00, p=0.13) and language of the child (χ2= 1.28, p= 0.52).

Parent's information

There was high significance between the levels of pain reduction with regard to the mother's education status

The "chi square test" showed that mothers with secondary education 11(100%) and graduates 2(100%) were benefited more having **"hurts little bit"** level of pain with **(χ2=12.27 p=0.01**)** describing high significance in the reduction of pain

There was no association in regard to the father's education (χ2=3.61, p=0.30), father's occupation (χ2=1.59, p=0.66), mother's occupation (χ2=1.29, p=0.52), family income (χ2=0.08, p=0.95), type of family (χ2=0.08, p=0.78) and the area of residence of the family (χ2=2.48, p=0.28).

Disease related information

There was no association between the level of pain reduction and family history of cancer (χ2=0.37 p=0.54)

Regarding the chemotherapy cycles there was significant reduction of pain among children who had more than three cycles of chemotherapy with **(χ2=8.67 p=0.03*).** Statistical significance was calculated by using **"chi square test".**

Van Cleve L, Johnson L, Pothier P (1996) conducted a study on pain responses of 90 hospitalized infants and children during intravenous cannulation. Data on physiological, behavioural, and subjective responses showed that changes in behaviour were significant in all age groups and the toddlers showed significant physiological change. The subjective measures showed that the children were able to identify their pain sites and intensity.

Lynn On.,(1988) conducted a study to assess the effectiveness of ice massage on the children's perception of pain during venepuncture. Eleven hospitalised children between the ages 7 to 16 years tested the two interventions that are routine venepuncture without ice massage and venepuncture with ice massage. Perception of pain was assessed by using 10 centimetres pain scale. The result indicated that there was less pain in venepuncture with ice massage compared to routine venepuncture without ice massage.

CHAPTER-VI
SUMMARY, IMPLICATIONS, RECOMMENDATIONS AND CONCLUSION

This chapter deals summary, implications, recommendations and conclusion of the study.

6.1 SUMMARY

The common nursing management for pain is providing comfort, distraction techniques, local hot and cold applications and application of local anaesthethic creams.

OBJECTIVES OF THE STUDY

- To assess the intensity of pain during intravenous cannulation routine care in children 5-12 years of age receiving intravenous chemotherapy in control group.
- To assess the intensity of pain during intravenous cannulation with ice pack application in children 5 -12 years of age receiving intravenous chemotherapy in experimental group.
- To compare the post-test level of pain between experimental and control group.
- To compare the effectiveness of ice pack application on pain reduction between experimental and control group.
- To associate the effectiveness of ice pack application on the reduction of pain with the selected demographic variables in experimental group.

The study was based on the assumption that

- Intravenous cannulation is a routine painful procedure in children.
- Topical ice pack application will reduce the intensity of pain during intravenous cannulation in children.

The research hypothesis formulated was:

H_1 : The mean pain score of experimental group after ice pack application will be significantly lower than the mean pain score of control group.

H_2 : There will be significant association between pain score of children with selected demographic variables.

The variables of the study were

Independent variable - Ice pack application.

Dependant variable **-** Pain during intravenous cannulation.

The review of literature was done from various primary and secondary sources that gave the basis for this study- for problem selection, formulation of objectives, development of tool, drawing the conceptual framework and planning for the method and duration of providing cryotherapy.

The investigator used ***Roy's Adaptation Theory*** as the base for drawing the conceptual framework of this study. This theory provided a comprehensive framework for achieving the objectives of the study.

The research design used for the study is ***True Experimental Study- Post-Test Only Control Group Design*** by ***Simple Random Sampling technique.***

The study was conducted at the ***Haematology ward, Institute Of Child Health and Hospital for Children, Egmore, Chennai-08.***

The tool consists of demographic profile and ***Wong Baker's faces pain scale***.

After getting the formal permission the pilot study was conducted at the haematology ward, Institute Of Child Health and Hospital for Children, Egmore, Chennai. The result revealed that topical ice pack application at the cannulation site had significant effect in reducing the intensity of pain in children during intravenous cannulation. The reliability of the tool was assessed by using inter-rater method and the correlation coefficient ***"r"*** value was ***0.87.*** This correlation coefficient was very high and found to be a good tool for assessing the effectiveness of cryotherapy in children during intravenous cannulation. It was also a cheap and practically feasible technique to proceed with the main study.

The main study was conducted at the Haematology ward, Institute Of Child Health and Hospital for Children, Egmore, Chennai, among 60 children who were receiving intravenous chemotherapy. The data collected was analysed by using "***Chi square test"*** and ***Student Independent "t"-test.***

6.2. MAJOR FINDINGS OF THE STUDY

The result showed that there was a significant difference in the of intensity of pain between the experimental group and control group during intravenous cannulation by prior topical application of ice pack at the cannulation site.

- With regard to the age, 8children (100%) between age groups 10-12 years were benefited more having ***"hurts little bit"*** level of

pain with ***$\chi 2=13.57$*** and ***p=0.01***** describing high significance in the reduction of pain.

- Regarding child's education, children 8(100%) of secondary school education were benefited having "hurts little bit" level of pain with ***$\chi 2=4.85$*** and ***p=0.03**** describing significance in the reduction of pain.

- Considering the mother's education status the children of mothers with secondary education 11(100%) and graduates 2(100%) were benefited more having ***"hurts little bit"*** level of pain with ***($\chi 2=12.27$ p=0.01**)*** describing high significance in the reduction of pain.

- Regarding the chemotherapy cycles there was significant reduction of pain among children who had more than three cycles of chemotherapy with ***($\chi 2=8.67$ p=0.03*)***

6.3. IMPLICATION

The investigator had drawn the following implications from the studies, which are of vital concern in the field of nursing practice, nursing administration, nursing education and nursing research.

NURSING PRACTICE

1) Paediatric pain management must have a more prominent place in the focus of care.

2) The use of ice pack application can be followed as an independent nursing intervention.

3) This intervention is economical, cost-effective, safe and easy to practice.

4) Cryotherapy-local ice pack application can be made to practice as a routine nursing care during intravenous cannulation.

NURSING ADMINISTRATION

1) The nurse administrator should encourage the nursing staffs to use topical ice pack application as a routine nursing care in the reduction of pain during intravenous cannulation.

2) The nursing administrator can organize conferences and in-service education programmes on various non-pharmacological measures in the reduction of pain.

3) The nurse administrator should supervise the nurse's application of ice pack for children receiving intravenous cannulation and also monitor the standards of practice

NURSING EDUCATION

1) The nurse educator should teach the nursing students about the techniques and the benefits of topical ice application during intravenous cannulation.

2) The nurse educator can motivate the students to do mini- projects on non-pharmacological measures to reduce pain in children during intravenous cannulation.

3) The nurse educator should conduct workshop, seminars and conferences on non-invasive complimentary therapies that help to update their knowledge to provide effective care.

4) The nurse educator should encourage the students to learn about the assessment of pain and the remedial measures to alleviate pain.

NURSING RESEARCH

1) The finding can be a baseline for further studies to improve the body of knowledge in nursing.

2) The nursing researcher should motivate the clinical nurse to do further research studies on topical ice application on pain reduction while carrying out various paediatric interventions.

3) The nursing researcher should encourage the clinical nurse to apply the research findings in their daily nursing care activities and can bring out new innovative procedures to reduce pain in children during intravenous cannulation.

4) The nurse administrator should conduct periodic review of research findings and disseminate the findings through conferences, seminars and publications in professional, national and international journals and also in the World Wide Web.

6.4. RECOMMENDATIONS

The study recommends the following for further research

- The similar study can be replicated with large samples for better generalization.
- A comparative study can be conducted to assess the effectiveness of topical ice application individually and in combination with other complementary therapies.
- A comparative study can be conducted to assess the effectiveness of topical cold application vs hot application in the reduction of pain during intravenous cannulation
- A study can be conducted to assess the effectiveness of ice application as a topical anaesthetic in other paediatric procedures.

6.5. CONCLUSION

The present study assessed the effectiveness of topical ice pack application at the cannulation site among children receiving intravenous chemotherapy. The results revealed that topical ice pack application had a significant effect in reducing the intensity of pain. Overall the children in the experimental group experienced minimum level of pain with ice pack application than the children in the control group who experienced more level of pain with routine care during intravenous cannulation.

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APPENDIX – I

SECTION A

I. CHILDREN DEMOGRAPHIC INFORMATION

Sample Number:____ Name of the child: _____

Diagnosis: _____

1. ***Age*** ☐
   a) 5 years -6 years
   b) 6 years -8years
   c) 8 years -10 years
   d) 10 years -12 years

2. ***Gender*** ☐
   a) Male
   b) Female

3. Religion ☐
   a) Hindu
   b) Muslim
   c) Christian
   d) Others

4. Birth order ☐
   a) One
   b) Two
   c) Three
   d) Three, specify

5. Language ☐
   a) Tamil
   b) Telugu
   c) Hindi
   d) others

6. Educational status ☐
   a) Uneducated
   b) No formal education
   c) Primary
   d) Secondary

II. **PARENTS DEMOGRAPHIC INFORMATION**

1. Educational status of the father ☐

a) Uneducated
b) Primary
c) Secondary
d) Graduate

2. Educational status of the mother ☐

a) Uneducated
b) Primary education
c) Secondary
d) Graduate

3. Occupation of the father ☐

a) Labourer
b) Self employed
c) Private
d) Government

4. Occupation of the mother ☐

a) House wife
b) Self employed
c) Private
d) Government

5. Income of the family ☐

a) Rs 4000 – Rs 6000
b) Rs 6001 – Rs 8000
c) Rs 8001 – Rs 10,000
d) Above Rs 10,000

6. Type of family ☐

a) Nuclear family
b) Joint family

7. Area of residence ☐

a) Rural
b) Urban
c) Semi-urban
d) Tribal

III.DISEASE RELATED INFORMATION

1. History of cancer to any others in the family ☐

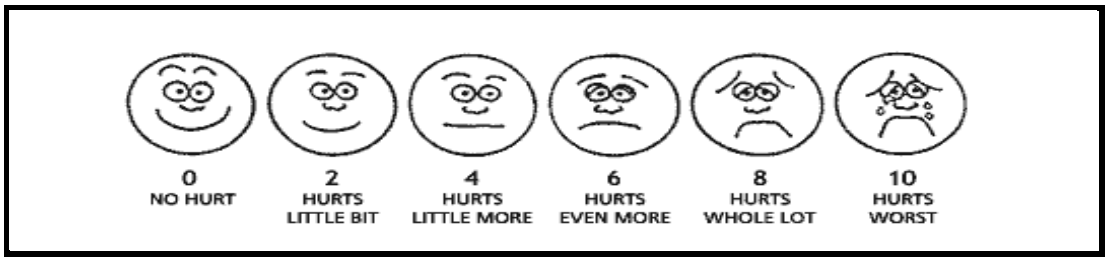
a) No
b) Yes , specify

2. What cycle of chemotherapy is the child getting now ☐

a) First
b) Second
c) Third
d) More than three, if so specify

SECTION -B

WONG –BAKER FACES PAIN RATING SCALE



SCORING:

The maximum total score is 10 with points ranging from 0 to 10

DESCRIPTION	*SCORE*
No hurt	0
Hurts Little Bit	2
Hurts little more	4
Hurts even more	6
Hurts whole lot	8
Hurts worst	10

INTERPRETATION

0 – No pain
1-2 – Mild
3-6 – Moderate
7-10 – Severe

PROCEDURE OF CRYOTHERAPY

Definition

Cryotherapy is defined as the local or general use of low temperatures as therapeutic modality in various medical and nursing treatments.

Purposes

1. To minimize pain perception and alleviates pain
2. To reduce the inflammation of tissues.
3. To reduce haemorrhage

Articles

A tray containing

S.NO	NAME OF THE ARTICLE	QUANTITY	PURPOSE
1.	Plastic container with lid	2	To take ice cubes and salt
2.	Plastic pouch	1	To make ice pack
3.	Flannel cloth	1	To cover the ice pack
4.	Mackintosh	1	To protect the bed linen
5.	Towel	1	To protect the bed linen
6.	Kidney tray	1	To receive waste

PROCEDURE

Topical application of ice pack at the cannulation site prior to intravenous cannulation .

Steps of the procedure

1. Established rapport with the child and the parents.
2. Explained the procedure to the child and the parents and obtained the informed consent from the parents.
3. Washed and dried up the hands.
4. Placed the child in the comfortable position (supine position)
5. Prepared the ice pack ((ice cubes sprinkled with a pinch of salt in a 5X5 centimeterplastic cover wrapped with 10X10centimeters flannel cloth).
6. Selected the vein for intravenous cannulation in the child's hand.
7. Applied ice pack in the arm 5 centimeters proximal to the cannulation site 15 seconds followed by intravenous cannulation.
8. Assessed the pain response of the child by using Wong Baker's faces pain scale.
9. The findings were documented for data analysis
10. Total duration for the procedure was around 10 minutes.

S.NO	INTERVENTION	DURATION
1.	Establishing rapport and obtaining informed consent	5 minutes
2.	Hand washing	30seconds
3.	Preparation of ice pack	1 minute
4.	Positioning of the child & selection of the vein for cannulation	1 minute
5.	Application of ice pack followed by intravenous cannulation	1 minute
6.	Replacement of articles	1minute
7.	Documentation	30 seconds

கேள்விப் படிவம்

பகுதி அ

I. குழந்தை பற்றிய அடிப்படைத் தகவல்கள்

மாதிரி எண்: _____ குழந்தையின் பெயர்: _____

நோயுறுதி: _____

1. வயது ☐
- அ. 5வயது - 6வயது
- ஆ. 6வயது - 8வயது
- இ. 8வயது - 10வயது
- ஈ. 10வயது - 12வயது

2. *பாலினம்* ☐
- அ. ஆண்
- ஆ. பெண்

3. *மதம்* ☐
- அ. இந்து
- ஆ. முஸ்லிம்
- இ. கிறிஸ்துவம்
- ஈ. மற்றவை

4. *பிறப்பு வரிசை* ☐
- அ. ஒன்று
- ஆ. இரண்டு
- இ. மூன்று
- ஈ. மூன்றுக்கு மேல், குறிப்பிடுக

5. *மொழி* ☐
- அ. தமிழ்
- ஆ. தெலுங்கு
- இ. ஹிந்தி
- ஈ. மற்றவை

6. *கல்வித் தகுதி* ☐
- அ. கல்வி அறிவற்றவர்
- ஆ. முறை சாராக் கல்வி
- இ. ஆரம்பக் கல்வி
- ஈ. உயர் நிலைக் கல்வி

II. பெற்றோர் பற்றிய அடிப்படைத் தகவல்கள்

1. *தந்தையின் கல்வித்தகுதி* 
   அ. கல்வி அறிவற்றவர்
   ஆ. ஆரம்பக் கல்வி
   இ. உயர் நிலைக்கல்வி
   ஈ. பட்டதாரி

2. *தாயாரின் கல்வித்தகுதி* 
   அ. கல்வி அறிவற்றவர்
   ஆ. ஆரம்பக் கல்வி
   இ. உயர் நிலைக்கல்வி
   ஈ. பட்டதாரி

3. *தந்தையின் தொழில்* 
   அ. கூலி
   ஆ. சுய தொழில்
   இ. தனியார்
   ஈ. அரசு வேலை

4. *தாயாரின் தொழில்* 
   அ. இல்ல நிர்வாகம்
   ஆ. சுய தொழில்
   இ. தனியார்
   ஈ. அரசு வேலை

5. *குடும்ப வருமானம்* 
   அ. ரூ4000 - ரூ 6000
   ஆ. ரூ 6001 - ரூ 8000
   இ. ரூ 8001 - ரூ 10,000
   ஈ. ரூ 10,000க்கு மேல்

6. *குடும்ப வகைப்பாடு* 
   அ. தனிக் குடும்பம்
   ஆ. கூட்டுக் குடும்பம்
   இ. விரிவான குடும்பம்
   ஈ. பிரிந்த குடும்பம்

7. **வசிக்குமிடம்** 
   அ. கிராமம்
   ஆ. நகரம்
   இ. நகர அருகாமை
   ஈ. பழங்குடி

III. நோய பற்றிய தகவல்கள்

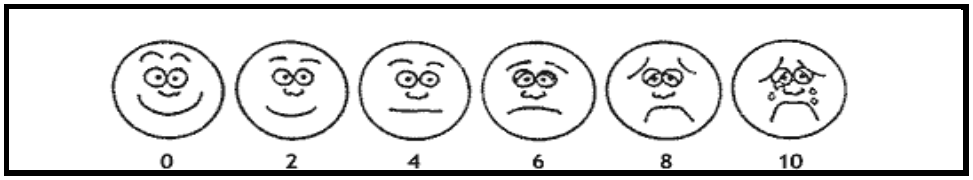
1. *புற்று நோயின் வரலாறு- ஏதேனும் மற்ற குடும் உறுப்பினர்களின்* ☐
   அ. இல்லை
   ஆ. ஆம், குறிப்பிடுக

2. *குழந்தையின் தற்போதைய கீமோதெரபி நிலை* ☐
   அ. முதல் சுற்று
   ஆ. இரண்டாம் சுற்று
   இ. மூன்றாம் சுற்று
   ஈ. மூன்றுக்கு மேல்- எனில் குறிப்பிடுக

பகுதி ஆ

வாங்பேக்கரின் முகக்குறி வலி அளவீட்டுக் கோல்

நோக்கம் : இந்த அளவுகோளானது குழந்தையின் வலிஉணர்வை அளப்பதாகும்.



மதிப்பீடு

விவரம்	*மதிப்பெண்*
வலிஇல்லை	0
மிகலேசானவலி	2
லேசானவலி	4
சிறிதுஅதிகவலி	6
அதிகவலி	8
கொடுமையானவலி	10

0 – வலிஇல்லை

1-2 – லேசானவலி

3-6 – மிதமானவலி

7-10 – கடுமையானவலி

Ir. No - 312 / C.O.N/M.M.C/CH.3 / Dt. 26.07.13

From

Mrs.S. Amutha,
M.Sc(Nursing) II year,
College of Nursing,
Madras Medical College,
Chennai-3.

To

The Professor & HOD of Hematology department,
Institute of Child Health and Hospital for Children,
Egmore,
Chennai-8.

Through Proper Channel,

Respected Madam,

Sub: Requesting Permission to conduct a research study-regarding

I, Mrs.S. Amutha, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission to conduct study for the proposed topic **"A study to assess the effectiveness of cryotherapy as topical anaesthetics prior to intravenous cannulation among children 5-12 years of age receiving Intravenous chemotherapy admitted in haematology ward, at Institute of Child Health, Egmore, Chennai-8."** to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Forwarded
26/07/13

Thanking you,

Date:

Yours obediently,

Place: Chennai - 03

(Mrs.S. Amutha)

30/7/13
Senior Civil Surgeon
Institute of Child Health and
Hospital for Children
Egmore, Chennai-600 008

Prof. V. THILAGAVATHI, M.D.,D.M.,(HAEM)
PROF. & HOD
DEPT. OF HEMATO - ONCOLOGY
GOVT. CHILDREN'S HOSPITAL
ICH & HC, CHENNAI - 600 008.

Lr. No. 293/ CON. MMC. Che 3/ Dt: 16/7/13

From

Mrs.S. Amutha,
M.Sc(Nursing) II year,
College of Nursing,
Madras Medical College,
Chennai-3.

To

The Director,
Institute of Child Health and Hospital for Children,
Egmore,
Chennai-8.

Through Proper Channel,

Respected Madam,

Sub: Requesting Permission to conduct a research study-regarding

I, Mrs.S. Amutha, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission to conduct study for the proposed topic **"A study to assess the effectiveness of cryotherapy as topical anaesthetics prior to intravenous cannulation among children 5-12 years of age receiving Intravenous chemotherapy admitted in haematology ward, at Institute of Child Health, Egmore, Chennai-8."** to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Forwarded
16/07/13

Thanking you,

Date: 16.07.13

Place: Chennai.

Yours obediently,

(Mrs.S. Amutha)

To the
HOD Haematology

Director and Superintendent
Institute of Child Health and
Hospital for Children
Egmore, Chennai - 600 008

CERTIFICATE OF CONTENT VALIDITY

This is to certify that a tool prepared by Mrs. S.Amutha, M.Sc. Nursing, II year of College of Nursing, Madras Medical College, undertaking a research study on "A study to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy admitted in haematology ward, Institute of Child Health, Egmore, Chennai-8". , has been validated by me and is found to be valid and up to date and she can proceed with this tool to conduct the main study.

Signature : 

Name : ZEALOUS MARY.C

Designation : READER

Date : 16.08.13

Place :

Seal : 

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

EC RegNo.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
S.Amutha,
M.Sc.,(N) II year,
College of Nursing,
Madras Medical College, Chennai-3.

Dear S.Amutha

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A study to assess the effectiveness of cryotherapy as topical anaesthethics prior to intravenous cannulation among children 5-12 years of age receiving Intravenous chemotherapy admitted in haematology ward, at Institute of Child Health, Egmore, Chennai-8" No.09072013.

The following members of Ethics Committee were present in the meeting held on 06.07.2013 conducted at Madras Medical College, Chennai -3.

1. Dr.G.SivaKumar, MS FICS FAIS --- Chairperson
2. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
3. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
4. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
5. Prof. Kalai Selvi -- Member
   Prof of Pharmacology, MMC, Ch-3
6. Prof. Siva Subramanian, -- Member
   Director, Instt. of Internal Medicine, MMC, Ch-3
7. Thiru. S. Govindsamy. BABL -- Lawyer
8. Tmt. Arnold Saulina MA MSW -- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandini

Member Secretary, Ethics Committee

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

புற்றுநோய் பிரிவில் உள்ள குழந்தைகளுக்கு நரம்பு ஊசி போடுவதற்கு முன்பு ஊசி போடுமிடத்தில் ஐஸ் கட்டி வைப்பதன் மூலம் வலி குறைகிறதா என்பதைப்பற்றிய திறனாய்வு

பங்குபெறுபவரின் பெயர்: வயது: தேதி: உள் நோயாளி எண்:

..... என்பவராகிய நான் இந்த ஆய்வின் விவரங்களும் அதன் நோக்கங்களும் முறையாக அறிந்துகொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுய நினைவுடன் பங்கு கொள்ள சம்மதிக்கிறேன்.

எனக்கு விளக்கப்பட்ட விஷயங்களைப் புரிந்துகொண்டு நான் எனது சம்மதத்தை தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தை பற்றி எனக்கு விளக்கப்பட்டது.

இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினை பற்றி அறிந்துகொண்டேன்.

இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின்பேரில் தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் பின்வாங்களாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்துகொண்டேன்.

இந்த ஆய்வில் கலந்துகொள்வதன் மூலம் என்னிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸ்ட்டியூசனல் எத்திக்ஸ் கமிட்டியிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

இந்த ஆய்வின் முடிவுகளை வெளியிடும்போது எனது பெயரோ, அடையாளோ வெளியிடப்படாது என அறிந்துகொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல்தாளைப் பெற்றுக்கொண்டேன்.

இந்த ஆய்வில் பங்கேற்கும்பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால், உடனே ஆய்வாளரை தொடர்புகொள்ள வேண்டும் என அறிந்துகொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்று தெரிந்துகொண்டேன்.

ஆராய்ச்சியாளர் கையொப்பம்

தேதி:

பங்கேற்பாளர் /பாதுகாவலர்/
பெற்றோர் கையொப்பம்/
தேதி:

CERTIFICATE OF CONTENT VALIDITY

This is to certify that a tool prepared by Mrs. S.Amutha, M.Sc. Nursing, II year of College of Nursing, Madras Medical College, undertaking a research study on "A study to assess the effectiveness of cryotherapy as topical ananesthetics prior to intravenous cannulation among children 5-12 years of age receiving intravenous chemotherapy admitted in haematology ward, Institute of Child Health, Egmore, Chennai-8". , has been validated by me and is found to be valid and up to date and she can proceed with this tool to conduct the main study.

Signature : V. Thilagavathi

Name : DR. V. THILAGAVATHI.

Designation : PROF. PAED HAEMATOLOGY.

Date : 30/8/13

Place : Chennai - 8

Seal :

Prof. V. THILAGAVATHI, M.D.,D.M.,(HAEM)
PROF. & HOD
DEPT. OF HEMATO - ONCOLOGY
GOVT. CHILDREN'S HOSPITAL
ICH & HC, CHENNAI - 600 008.